VS-800

Vital Signs Monitor

Operator’s Manual

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CE 0123

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Preface

Manual Purpose

This manual provides the instructions necessary to operate the VS-800 Vital Signs Monitor (hereinafter called as this monitor) in accordance with its function and intended use. Observance of this manual is a prerequisite for proper performance and correct operation, and ensures patient and operator safety.

This manual is written based on the maximum configuration. Part of this manual may not apply to your monitor. If you have any question about the configuration of your monitor, please contact our Customer Service.

This manual is an integral part of and should always be kept close to the monitor, so that it can be obtained conveniently when necessary.

Intended Audience

This manual is geared for the clinical medical professionals. Clinical medical professionals are expected to have working knowledge of medical procedures, practices and terminology as required for monitoring of patients.

Version Information

This manual has a version number. This version number changes whenever the manual is updated due to software or technical specification change. Content of this manual is subject to change without prior notice. The version information of this manual is as follows.

Version number	Release date
2.4	October 2007

Illustrations and Names

All illustrations in this manual are provided as examples only. They may not necessarily accord with the graphs, settings or data displayed on your monitor.

All names appeared in this manual and illustrations are fictive. It is a mere coincidence if the name is the same with yours.

Conventions

- ***Italic*** text is used in this manual to quote the referenced chapters or sections.
- The terms danger, warning, and caution are used throughout this manual to point out hazards and to designate a degree or level or seriousness.

1 Safety

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1.1 Safety Information

The safety statements presented in this chapter refer to the basic safety information that the operator of the monitor shall pay attention to and abide by. There are additional safety statements in other chapters or sections, which may be the same as or similar to the followings, or specific to the operations.

⚠DANGER

- **Indicates an imminent hazard situation that, if not avoided, will result in death or serious injury.**

⚠WARNING

- **Indicates a potential hazard situation or unsafe practice that, if not avoided, could result in death or serious injury.**

⚠CAUTION

- **Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.**

NOTE

- **Provides application tips or other useful information to ensure that you get the most from your product.**

1.1.1 Dangers

There are no dangers that refer to the product in general. Specific “Danger” statements may be given in the respective sections of this operation manual.

1.1.2 Warnings

⚠WARNING

- **This monitor is not applicable for prolonged and continuous SpO_2 monitoring, which may increase the risks of irritation and burns at the site of the sensor.**
- **This monitor is not applicable for prolonged and continuous temperature monitoring for more than 5 minutes.**
- **This monitor is intended for use by qualified clinical physicians or well-trained nurses in the specified places.**
- **It is your responsibility to verify the device and accessories can function safely and normally before use**
- **The disposable accessories should be disposed of in accordance with the hospital regulations.**
- **A possible fire or explosion hazard exists when used in the presence of flammable anesthetics or other flammable or explosive substances in combination with air, oxygen-enriched environments, or nitrous oxide.**
- **You must customize the alarm setups according to the individual patient situation, and make sure the alarm sound can be activated when an alarm occurs.**
- **Opening the monitor housing presents a risk of hazard due to electrical shock. All servicing and future upgrades to this equipment must be carried out by personnel tranined and authorized by Mindray only.**
- **Do not touch the patient during defibrillation. A risk of serious injury or death is present.**
- **When used in conjunction with electro-surgery equipment, you must give top priority to the patient safety.**
- **Dispose of the package material, observing the applicable waste**

control regulations and keeping it out of children's reach.

- **The device must be connected to a properly installed power outlet with protective earth contacts only. If the installation does not provide for a protective earth conductor, disconnect the monitor from the power line and operate it on battery power, if possible.**

1.1.3 Cautions

⚠CAUTION

- **To ensure patient safety, use only parts and accessories specified in this manual.**
- **Remove the battery from the monitor if it will not be used or not be connected to the power line for a long period.**
- **Disposable devices are intended for single use only. They should not be reused as performance could degrade or contamination could occur.**
- **At the end of its service life, the product described in this manual, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have any questions concerning disposal of the products, please contact with us.**
- **Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the monitor comply with the relevant EMC requirements. Mobile phone, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.**
- **Before connecting this monitor to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the label or in this manual.**
- **Install or carry the monitor properly to avoid damages caused by drop, impact, strong vibration or other mechanical force.**

1.1.4 Notes

NOTE

- **Keep this manual close to the monitor so that it can be obtained conveniently when necessary.**
- **This monitor complies with the requirements of CISPR11 (EN55011) class A.**
- **The software was developed per IEC60601-1-4. The possiblility of hazards arising from errors in software program is minimized.**
- **Put the monitor in a location where you can easily see the screen and access the operating controls.**
- **The instructions of this manual are based on the maximum configuration. Some of them may not apply to your monitor.**

1.2 Equipment Symbols

	Caution: Consult accompanying documents (this manual).		Up
	Power ON/OFF		Selection
	Alternating current (AC)		Down
	Battery indicator		Pulse Rate (PR)
	Defibrillation-proof type CF applied part		Neonate
	NIBP		Pediatric/Child
	PATIENT INFO.		Adult
	MENU		Equipotentiality
	SET ALARMS		(Nurse call) Output
	DISPLAY		RS-232 connector
	INTERVAL		Date of manufacture
	RECORD		Serial number
	SILENCE		Network connector
	CE marking		

1.3 CE Marking

The vital signs monitor bears CE mark CE-0123 indicating its conformity with the provision of Council Directive 93/42/EEC concerning medical devices, and fulfills the essential requirement of Annex I of this directive.

This monitor is in radio-interfernce protection class A in accordance with EN55011.

The product complies with the requirement of standard EN60601-1-2 "Electromagnetic Compatibility – Medical Electrical Equipment".

1.4 Reference Literature

1. COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices
2. IEC60601-1 or EN60601-1, Medical Electrical Equipment, Part 1: General Requirements for Safety
3. IEC60601-1-1 or EN60601-1-1, Medical Electrical Equipment- Part 1-1: General Requirements for Safety - Collateral Standard: Safety Requirements for Medical Electrical Systems
4. IEC60601-1-4, Medical Electrical Equipment- Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems.
5. IEC60601-2-49, Medical Electrical Equipment-Part 2-49: Particular Requirements for the Safety of Multifunction Patient Monitoring Equipment.

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2.1 Monitor Description

2.1.1 Intended Use

This Monitor is intended for monitoring the patient's vital signs including Non-invasive Blood Pressure (NIBP), Pulse Oxygen Saturation (SpO_2), Pulse Rate (PR) and Temperature (TEMP) for single adult, pediatric and neonatal patient.

This Monitor is intended for use in the health-care institutions such as Outpatient Clinics, Emergency Departments, Medical Floors, Clinics and Nursing Departments. It, however, is not intended for critical patient monitoring, hospital transport or home use.

⚠WARNING

- **This Monitor is to be operated by clinical physicians or appropriate medical staffs under the direction of physicians. The operator of the monitor must be well tranined. Any operation by unauthorized or non-tranined personnel is forbidden.**
- **The physiological parameters and the alarm information displayed by the monitor are only for the reference of physicians, but cannot be used directly to determine the clinical treatment.**

⚠CAUTION

- **The environment and power supply of this monitor must meet the requirements specified in *Appendix A Product Specifications*.**

2.1.2 Contraindications

None

2.1.3 Components

This monitor is composed of a main unit, NIBP cuff, SpO_2 sensor and TEMP probe. Note that some of the mentioned parts are optional and may not be found on your monitor.

2.1.4 Functions

This monitor has the following functions and features:

- SpO_2 measurement: pulse oxygen saturation (SpO_2), pulse rate (PR), and SpO_2 plethysmogram.
- NIBP measurement: systolic pressure (S), diastolic pressure (D), mean pressure (M), and pulse rate (PR).
- TEMP measurement: temperature (TEMP).
- Alarm: support visual/audible alarm and prompt message.
- Record: support the function of recording NIBP trend data and PLETH waveforms.
- Nurse call.
- Storage of trend data: support the function of storing up to 1200 groups of measured results.
- Powerful system menu.
- Large LED digit display.
- AdjustableLCD brightness and contrast.
- Network communication: support the function of being connected to the CMS or PC for data output or online upgrade.
- Rechargeable lead-acid battery or lithium battery.

2.2 Appearance

2.2.1 Front Panel

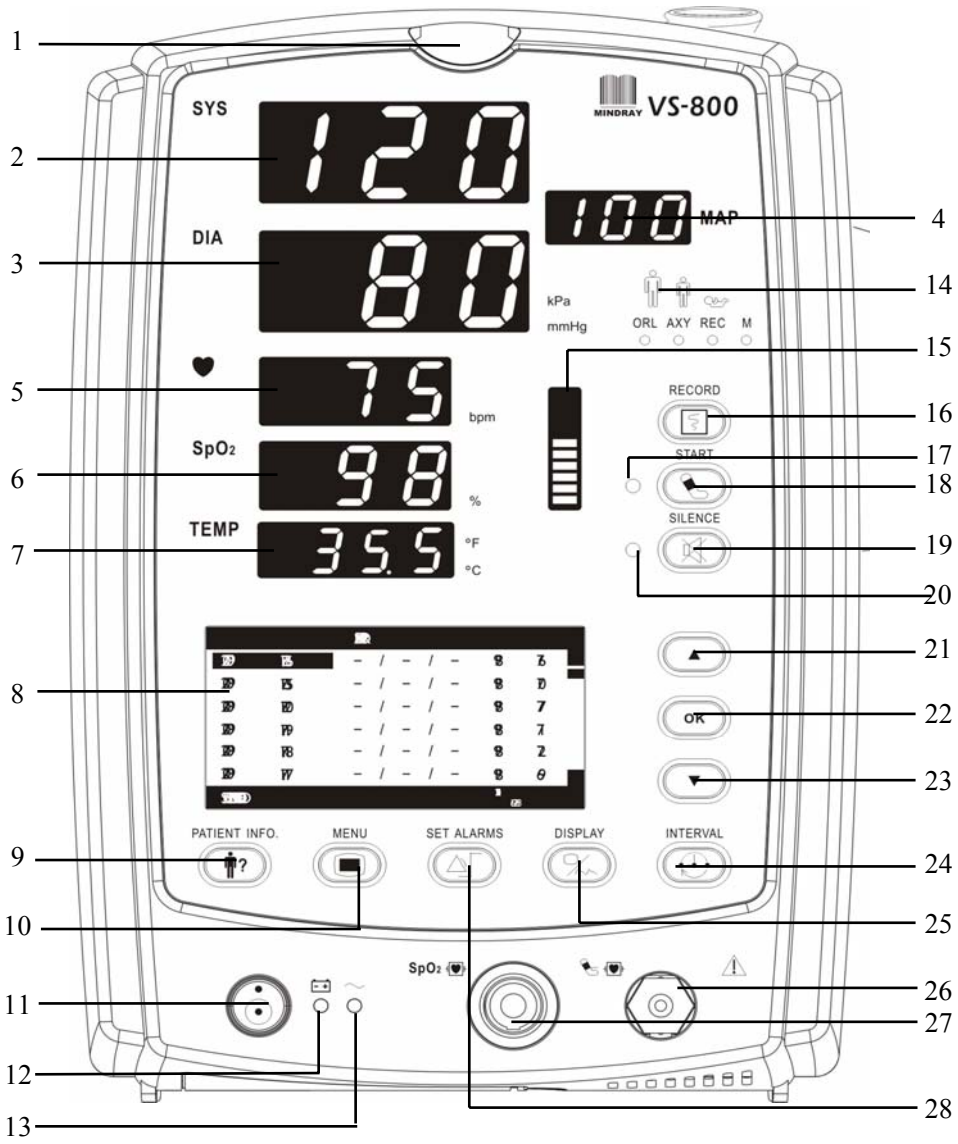

Figure 2-1 Front Panel

1. Alarm indicator

The alarm indicator of this monitor is in compliance with the requirement of EN60825-1 A11 Class 1 for LED. The LED indicator varies its flash color and frequency to indicate different alarm levels. For details, refer to ***5.2.1 Visual Alarms***.

2. SYS

This LED digit displays the systolic pressure reading in the NIBP measurement.

3. DIA

This LED digit displays the diastolic pressure reading in the NIBP measurement. At the right side of the NIBP reading, it is the NIBP unit: kPa or mmHg. NIBP UNIT can be set in the system setup menu and the one flashes is the unit selected.

4. MAP

This LED digit displays the mean pressure reading in the NIBP measurement.

5. PR

This LED digit displays the PR value in the NIBP measurement or SpO_2 measurement, with the unit (bpm) on the right.

6. SpO_2

This LED digit displays the SpO_2 value, with the unit (%) on the right.

7. Temp

This LED digit displays the temperature reading. At the right side of the NIBP reading, it is the TEMP unit: ℃ or ℉. TEMP UNIT can be set in system setup menu and the one flashes is the unit selected

8. LCD

The LCD displays menus, trend data or PLETH trend graphs.

9. PATIENT INFO.

Press this key to switch between the PATIENT INFORMATION menu and the trend table.

10. MENU

Press this key to switch between the SYSTEM SETUP menu and the trend table.

11. On/standby, working status indicator

Press this key to power on/off the monitor and to enter/exit the standby state. To power off the monitor, press this key for more than 2 seconds.
Inside this key is a working status indicator:

- ON: It indicates that the monitor is powered on;
- OFF: It indicates that the monitor is powered off.

12. Battery indicator

It indicates the status of the battery. For details, refer to ***2.4 Battery***.

13. AC power indicator

- ON: It indicates that the AC power is applied to the monitor;
- OFF: It indicates that the monitor is not applied to the monitor.

14. Patient type indicator

It indicates the patient types: adult, pediatric or neonate.

15. Pulse strength indicator

It indicates the pulse strength of a patient.

16. RECORD

Press this key to start or stop the printing (recording).

17. NIBP status indicator

- ON: It indicates that the monitor is performing the NIBP measurement;
- OFF: It indicates that the monitor is not performing the NIBP measurement.

18. NIBP

Press this key to start an NIBP measurement, or press this key during measurement to stop it.

19. SILENCE

Press this key to start a 2-minute alarm pause. Wihin the alarm pause time, the system will return to the normal status when a new alarm occurs. Press this key for more than 2 seconds to disable all sounds or tones of the system, thus entering the silience mode.

20. Silence indicator

- OFF: normal status; in this status, when an alarm occurs, the system can give an audible alarm according to the alarm level;
- ON: system silenced status; in this status, the system cannot give any sound, including audible alarm, key tone, and pulse tone.
- FLASH: alarm paused status; in this status, the system cannot give the audible and visual alarm.

21. Up

Press this key to move the cursor upward.

22. OK

Press this key to select the highlighted option.

23. Down

Press this key to move the cursor down.

24. INTERVAL

Press this key to switch between the INTERVAL menu and the trend table.

25. DISPLAY

Press this key to switch between the PLETH (plethysmogram) waveform and trend table.

26. NIBP cuff connector

This connector is used to connect the NIBP cuff to the monitor.

27. SpO_2 sensor connector

This connector is used to connect the SpO_2 sensor to the monitor.

28. SET ALARMS

Press this key to switch between the SET ALARMS menu and the trend table.

2.2.2 Rear Panel

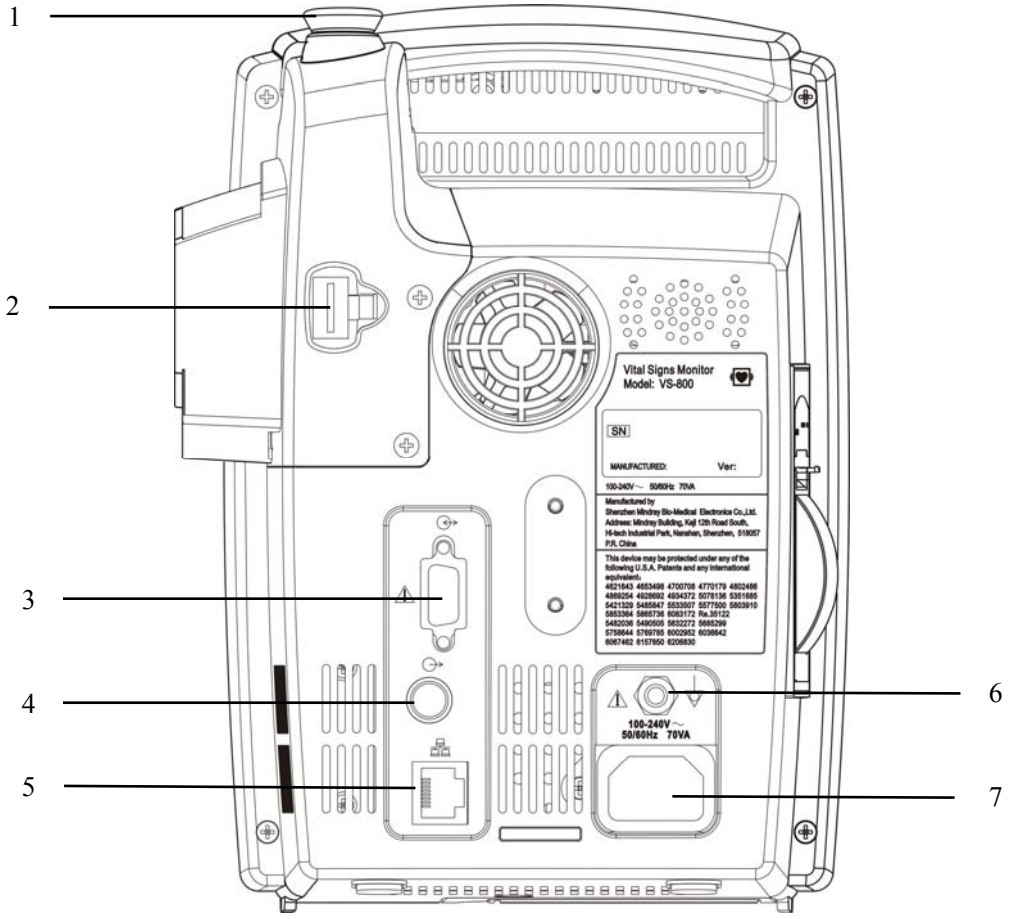

Figure 2-2 Rear Panel

1. TEMP probe sheath
2. TEMP probe connector
3. RS-232 connector:
4. Nurse call connector: used to connect the monitor to the nurse call system in hospital.
5. Network connector: used to connect the monitor to the CMS(and CMS+) or PC.
6. Equipotential grounding connector: connects the equipotential grounding connectors of other devices.
7. AC power input connector: used to connect the monitor to the AC power through a 3-core power cable.

2.2.3 Recorder

The recorder is on the left side of the monitor. See the following figure.

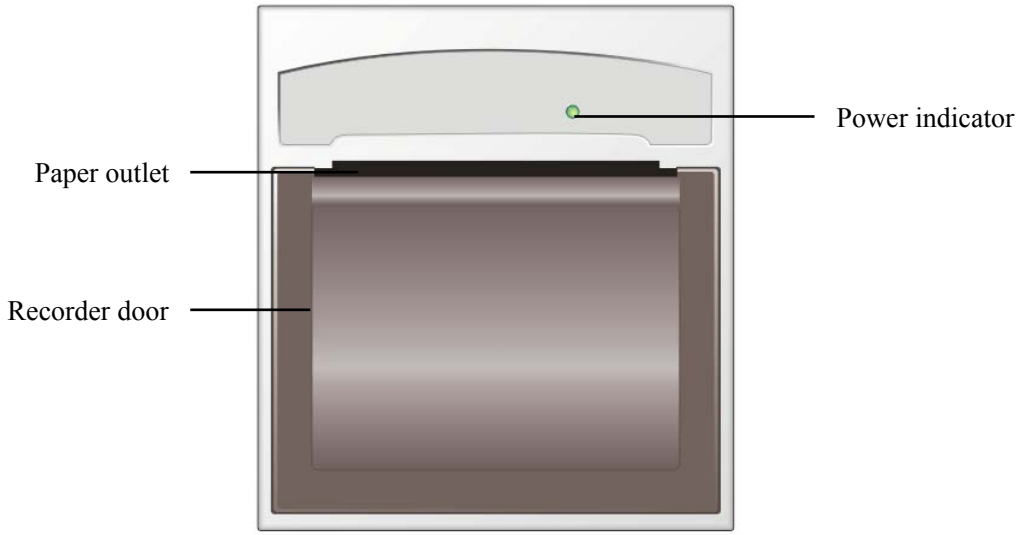

Figure 2-3 Recorder

For details about the recorder, refer to ***6 Recording***.

2.3 Display

Figure 2-4 Display

This monitor adopts the LCD display. It is able to display the following three parts:

1. Title bar

In the title bar are menus or screen titles.

2. Main display area

In the main display area are menus, trend data or plethysmogram (PLETH for short) waveforms.

3. Notification area

On the left of the notification area is the technical alarm message or prompt message. If there are multiple messages, they will be displayed here in turns.
On the right of the notification area are the patient ID and current system time.
When a pysiological alarm occurs, the pysiological alarm message, patient ID and system time will be displayed here in turns; when an alarm pause is started, the system will prompt “ALARM PAUSED XXX s”.

2.3.1 Cursor

In menus or trend data screens, when the cursor moves to an option or a data, the background of the option or the data will become black and the fonts will become white. You can press ▲ or ▼ to move the cursor, and press OK to select the highlighted option or data for the next the operation.

NOTE

- **▲ and ▼ are used to move the cursor, and OK is used for “Selection”.**

2.4 Battery

Rechargeable batteries can be used to supply power to the monitor for transport or whenever the power supply is interrupted. The battery is charged automatically when the monitor is connected to AC mains till it is full. If the power supply is lost during monitoring, the monitor can run on the power supplied by the internal battery.

The battery indicator indicates the status of the battery.

- ON: The battery is being charged or the battery is fully charged.
- OFF: The battery is removed from the monitor or the battery in the monitor is depleted. If the monitor is equipped with battery but is not connected to AC mains and not turned on, the indicator will also be off.
- Flashes: The indicator light flashes when the monitor is powered by the internal battery.

The capacity of the internal battery is limited. When the battery capacity is too low, a high level alarm is triggered and the "Battery too low" message is given in the technical alarms area. At this moment, the AC mains shall be applied to the monitor; otherwise the monitor will power off automatically before the battery is depleted.

For details about installation of the battery, refer to ***3.1.5 Installation Method***:***Installing the battery***.

NOTE

- **Remove the battery before transport, or if the monitor is not likely to be used for an extended period of time.**

⚠WARNING

- **Keep the battery out of the reach of children.**
- **Use only the battery specified by the manufacturer.**

2.4.1 Battery Maintenance

Conditioning a Battery

A battery should be conditioned before it is used for the first time. A battery conditioning cycle is one uninterrupted charge of the battery, followed by an uninterrupted discharge of the battery. Batteries should be conditioned regularly to maintain their useful life. Condition a battery once when it is used or stored for two months, or when its run time becomes noticeably shorter.

To condition a battery, follow this procedure:

1. Disconnect the monitor from the patient and stop all monitoring or measuring.
2. Insert the battery in need of conditioning in the battery slot of the monitor.
3. Apply AC power to the monitor and allow the battery to charge uninterrupted for 10 hours.
4. Remove AC power and allow the monitor to run from the battery until it shuts off.
5. Apply AC power again to the monitor and allow the battery to charge uninterrupted for 10 hours.
6. This battery is now conditioned and the monitor can be returned to service.

Checking a Battery

The performance of a rechargeable battery may deteriorate over time. To check the performance of a battery, follow this procedure:

1. Disconnect the monitor from the patient and stop all monitoring or measuring.
2. Apply AC power to the monitor and allow the battery to charge uninterrupted for 10 hours.
3. Remove AC power and allow the monitor to run from the battery until it shuts off.
4. The operating time of battery reflects its performance directly.

If your monitor has two battery slots, you can check two batteries at the same time. Please replace the battery or contact with the maintenance personnel if its operating time is significantly lower than the specified time.

NOTE

- **Life expectancy of a battery depends on how frequent and how long it is used. For a properly maintained and stored lead-acid or lithium ion battery, its life expectancy is about 2 or 3 years respectively. For more aggressive use models, life expectancy can be less. We recommend replacing lead acid batteries every 2 years and lithium ion batteries every 3 years.**
- **The battery might be damaged or malfunctioned if its operating time is too short after being fully charged. The operating time depends on the configuration and operation. For example, measuring NIBP more frequently will also shorten the operating time.**

2.4.2 Battery Recycling

When a battery has visual signs of damage, or no longer holds a charge, it should be replaced. Remove the old battery from the monitor and recycle it properly. To dispose of the batteries, follow local laws for proper disposal.

⚠WARNING

- **Do not disassemble batteries, or dispose of them in fire, or cause them to short circuit. They may ignite, explode, leak or heat up, causing personal injury.**

FOR YOUR NOTES

3 Installation and Maintenance

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3.1 Installation

⚠WARNING

- **The installation of the monitor must be carried out by personnel authorized by Mindray. The software copyright of the monitor is solely owned by our company. Any action to change, copy or exchange the software by any organization or person is regarded as copyright infringement and is not allowed.**

3.1.1 Unpacking and Checking

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier or our company.

If the packing case is intact, open the package and remove the instrument and accessories carefully. Check all materials against the packing list and check for any mechanical damage. Contact our Customer Service Department for any problem.

NOTE

- **Please save the packing case and packaging material for future transport and storage.**

⚠WARNING

- **Dispose of the packaging material, observing the applicable waste control regulations and keeping it out of children's reach.**
- **The equipment might be contaminated in storage, transport or when used. Verify the package and the single use accessories are intact. In case of any damage, do not apply it to patients.**

3.1.2 Environmental Requirements

The operating environment of the monitor must meet the requirements specified in the section ***A.2Environmental Specifications*** of ***Appendix A Product Specifications***.

The environment where this monitor is to be used should be free from noise, vibration, dust, and corrosive or explosive and inflammable substances. For a cabinet mounted installation, allow sufficient room at the front and the rear of the cabinet for operation, maintenance and servicing. Besides, allow at least 2 inches clearance around the instrument for proper air circulation.

Condensation can form when the monitor is moved from one location to another, and being exposed to differences in humidity or temperature. Make sure that during operation the instrument is free from condensation.

3.1.3 Power Supply Requirements

The power applied to the monitor must meet the requirements specified in the section ***A.3Power Requirements*** of ***Appendix A Product Specifications***.

⚠WARNING

- **Make sure that the operating environment and the power applied to the monitor comply with the specified requirements. Otherwise its performance might not meet the specifications claimed in *Appendix A Product Specifications*, and unexpected results, such as damages to the monitor, may be incurred.**
- **The monitor shall be powered according to the requirement for the system power voltage. Otherwise, serious damage might be caused to the system.**

3.1.4 Bracket Mounting

For details, please refer to the corresponding instructions for use of bracket mounting

3.1.5 Installation Method

⚠WARNING

- **Accessory equipments connected to this monitor must be certified according to the respective IEC standards (e.g. IEC 60950 for information technology equipment and IEC 60601-1 for medical electrical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC 60601-1-1. Any person who connects additional equipment to the signal input or signal output is responsible to ensure the system complies with the requirements of the valid version of the system standard IEC 60601-1-1. If in doubt, contact our company or customer service.**
- **If the monitor is connected to another electrical instrument and the instrument specifications cannot tell whether the instrument combination is hazardous (e.g. due to summation of leakage currents), you should consult Mindray or experts in the field to ensure the required safety of all instruments concerned.**

NOTE

- **The following operations are not all required. User-customized installation by authorized personnel is provided.**

Connecting to AC mains

1. Use the original 3-core power cable.
2. Connect the power cable to the AC mains input connector on the rear panel of the monitor.
3. Connect the other end of the power cable to a compatible 3-prong hospital grade AC power outlet.

The 3-prong power outlet must be grounded. In case of any doubt, contact related personnel of the hospital.

⚠WARNING

- **Do not use three-wire to two-wire adapter with this instrument.**
- **To avoid unexpected power interruption, do no use power outlet with a wall-mounted switch control.**

Installing the battery

The battery compartment is located at the bottom of the patient monitor. Follow the steps given below to install the battery.

1. Push the compartment door in the marked direction to open the door.
2. Flip the battery stopper to the left, as Figure 3-1 shows.
3. Follow the marked polarity to insert the battery into the compartment, as Figure 3-2shows.
4. Push the battery all the to the bottom and flip the stopper back to the original position, as Figure 3-3 shows.
5. Close the battery door.

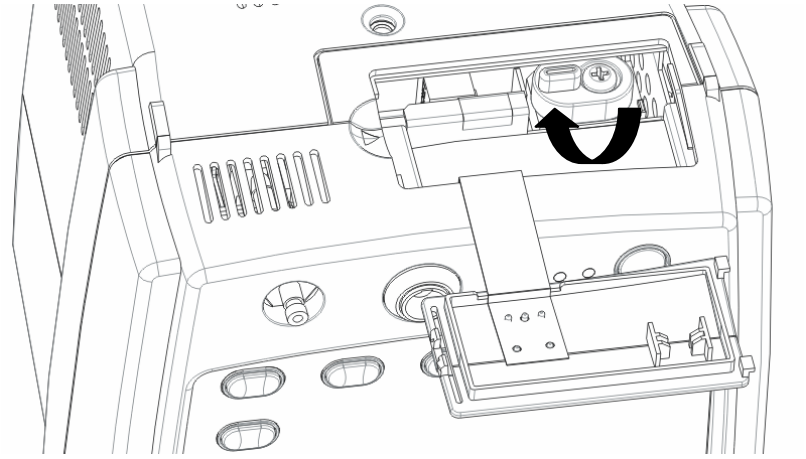

Figure 3-1

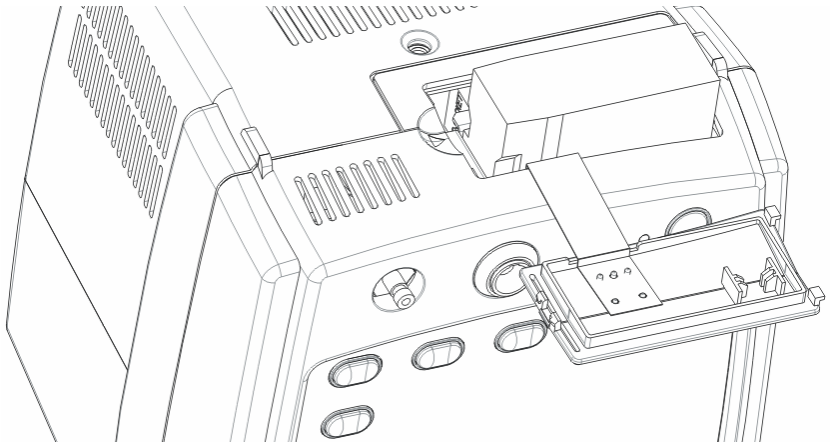

Figure 3-2

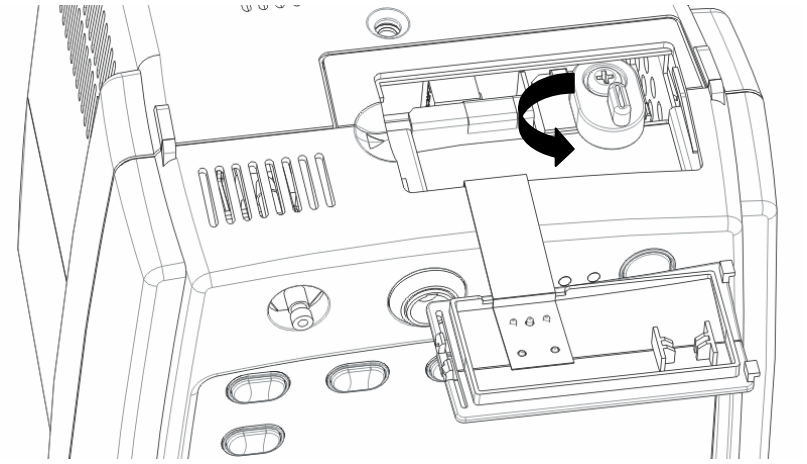

Figure 3-3

NOTICE

- **Be sure to charge the battery after a long-term storage or when you find the battery energy is low. A low-energy battery may not provide enough power to start the patient monitor.**
- **To charge the battery, connect the AC power to the monitor. The battery will be charged regardless the monitor is on or off.**

Equipotential Grounding

When other equipments are used together with the monitor, a grounding cable should be used to connect the equipotential grounding connectors of the monitor and of other equipments. This helps to reduce the potential differences between different pieces of equipment, and ensure the safety of the operator and patient.

⚠WARNING

- **If the grounding system is in doubt, the monitor must be supplied from its internal battery.**

Connecting the accessories

Connect the necessary sensors or probes to the monitor. For details, see the chapters for specific parameter monitoring in the following pages, or corresponding instructions for sensors and probes.

Connecting the network cable

The network connector of the monitor is a standard RJ45 connector. It connects the monitor with the central monitoring system, or with a PC for online upgrade or data output.

1. Connect one end of the network cable to the network connector of the monitor.
2. Connect the other end of the network cable to the hub of the central monitoring system, or to the network connector of a PC.

⚠WARNING

- **The system upgrading through the network connector is to be executed by Mindray authorized personnel only.**

Nurse call connector

The nurse call connector is used for the nurse call function. If connected to the nurse call system of the hospital through a special nurse call cable, the monitor can generate nurse call signals when alarms occur. The output end of the nurse call cable consists of two free cords that is neutral. The installation should be done according to the nurse call system by the maintenance engineer from the manufacturer or the engineer of the hospital.

⚠WARNING

- **This Monitor is to be operated by clinical physicians or appropriate medical staffs under the direction of physicians. The operator of the monitor must be well trained. Any operation by unauthorized or non-trained personnel is forbidden.**

3.1.6 Powering on the Monitor

After installing the monitor, please power on it in the following procedure:

1. Before using the monitor, please carry out corresponding safety inspection in accordance with 3.2.1 Inspection.
2. Press the Power Switch on the control panel. A beep will be heard.
3. The system starts self-test and the start-up screen will be displayed.
4. Several seconds later, the system finishes the self-test and displays the main screen.
5. Then you can operate the monitor through the control panel.

3.1.7 Powering off the Monitor

To power off the monitor, please follow the procedures below:

1. Confirm the patient monitoring is to be finished.
2. Disconnect the cables and sensors between the monitor and the patient.
3. Confirm whether to store or clear the patient monitoring data.
4. Press the Power switch and hold it for more than 2 seconds to power off the monitor.

3.2 Maintenance

⚠WARNING

- **Failure on the part of the responsible hospital or institution employing the monitoring equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazard.**
- **The safety inspection before equipment disassembly or the servicing of the equipment must be performed by professional servicing personnel. Otherwise, equipment failure and possible health hazard may be caused.**

3.2.1 Inspection

Make sure the qualified service personnel have implemented a complete inspection before putting the monitor into operation, after monitor servicing or system upgrading, or after the monitor has been used for 6-12 consecutive months. This is to ensure the normal operation of the system.

Check whether

- The environment and the power supply meets the specified requirements.
- The monitor cover is free from stains.
- The monitor cover, keys, connectors and accessories are physically damaged.
- The power cords are worn and the insulation is in good performance.
- The grounding cables are properly connected.
- Only specified accessories like electrodes, sensors and probes are applied.
- The monitor clock is correct.
- The audible and visual alarms are normal.
- The recorder functions normally and the recorder paper meets the requirement.
- The monitoring functions of the system are in good performance.

In case of any damage or exception, do not use the monitor. Contact the biomedical engineers of the hospital or our Customer Service immediately.

3.2.2 Cleaning

⚠WARNING

- **Be sure to shut down the system and disconnect all power cords from the outlet before cleaning the equipment.**

Your equipment should be cleaned regularly. If there is heavy pollution or lots of dust and sand in your place, the equipment should be cleaned more frequently. Before cleaning the equipment, consult your hospital's regulations for cleaning, disinfecting and sterilizing equipment.

The exterior surfaces of the equipment may be cleaned with a clean and soft cloth, sponge or cotton ball, dampened with a non-erosive cleaning solution. Drying off excess cleaning solution before cleaning the equipment is recommended. Following are examples of cleaning solutions:

- Diluted soap water
- Diluted ammonia water
- Diluted sodium hyoichlo (bleaching agent)
- Diluted formaldehyde (35 to 37%)
- Hydrogen peroxide (3%)
- Ethanol (70%), or Isopropanol (70%)

NOTE

- **The ssodium hypochlorite of the concentration ranging from 500ppm (1:100 diluted bleaching agent for home use) to 5000ppm (1:10 diluted bleaching agent for home use) is effective. The required concentration depends on the quantity of the organic substances (such as blood, mucus) on the equipment surface.**

To avoid damage to the equipment, please follow these rules:

- ALWAYS dilute the solutions according to the manufacturer's suggestions.

- ALWAYS wipe off all the excess cleaning solution with a dry cloth after cleaning.
- NEVER submerge the equipment into water or any cleaning solution, or pour or spray water or any cleaning solution on the equipment.
- NEVER permit fluids run into the casing, switches, connectors, or any ventilation openings in the equipment.
- NEVER use abrasive or erosive cleaners of any kind as well as cleaners containing acetone.

⚠CAUTION

- **Failure to follow these rules may erode or fray the casing, or blur lettering on the labels, or cause equipment failures.**

For cleaning information of accessories, please refer to the chapters for specific patient parameters and the instructions for use of the accessories.

3.2.3 Disinfection

⚠WARNING

- **Disinfection or sterilization may cause damage to the equipment; therefore, when preparing to disinfect or sterilize the equipment, consult your hospital's infection controllers or professionals.**
- **The cleaning solutions above can only be used for general cleaning. If you use them to control infections, we shall assume no responsibility for the effectiveness.**

Disinfection may cause damage to the equipment. We recommend the sterilization and disinfection are contained in the hospital's servicing schedule only when necessary. The equipment should be cleaned prior to sterilization and disinfection.

Recommended sterilization material: Alcohol based (Ethanol 70%, Isopropanol 70%), and aldehyde based.

⚠WARNING

- **ALWAYS dilute the solutions according to the manufacturer's suggestions and adopt lower concentration if possible.**
- **NEVER submerge the equipment into water or any solution, or pour water or any solution on the equipment.**
- **ALWAYS wipe off all the excess liquids on the equipment surface and accessory surface with a dry cloth.**
- **NEVER use EtO and formaldehyde to disinfect the equipment.**
- **Never permit high-pressure and high-temperature disinfection of the equipment and accessories.**

4 Menus and Screens

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4.1 Patient Information Setup

By pressing , you can open the PATIENT INFORMATION menu (see the following figure), and by pressing this key again, you can switch to the trend data screen.

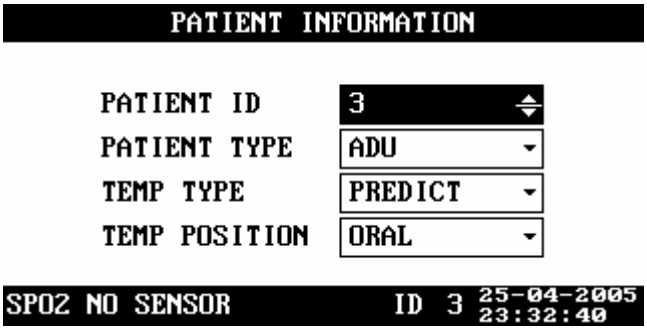

Figure 4-1

In the PATIENT INFORMATION menu, you can set

- PATIENT ID: 1 - 100
- PATIENT TYPE: ADU (adult), NEO (neonate), PED (pediatric)
- TEMP TYPE: PREDICT, MONITOR
- TEMP POSITION: ORAL, AXILLARY, RECTAL. TEMP POSTION displays on the LED DISPLAY by an icon.

To set the patient information

, and are used for moving the cursor and selecting the highlighted option. They are most frequently used keys in menu operations. Take the patient type setup as an example:

1. In the PATIENT INFORMATION menu, press or to move the cursor to the option on the right of PATIENT TYPE.
2. Press to select this option.
3. Press or to select the patient type as required.
4. Press to confirm the selected patient type.

4.2 System Setup

By pressing on the front panel of the monitor, you can open the SYSTEM SETUP menu (See the following figure).

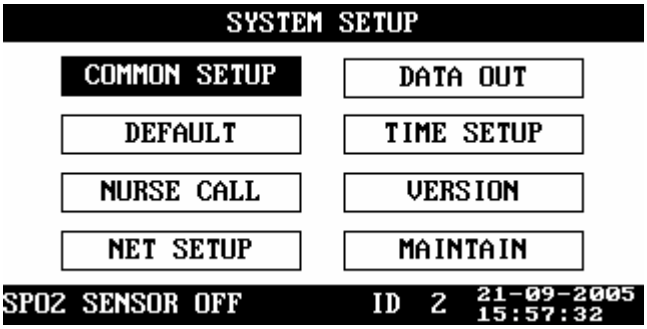

Figure 4-2

4.2.1 Common Setup

In the SYSTEM SETUP menu, select COMMON SETUP. The COMMON SETUP menu appears, as shown in the following figure.

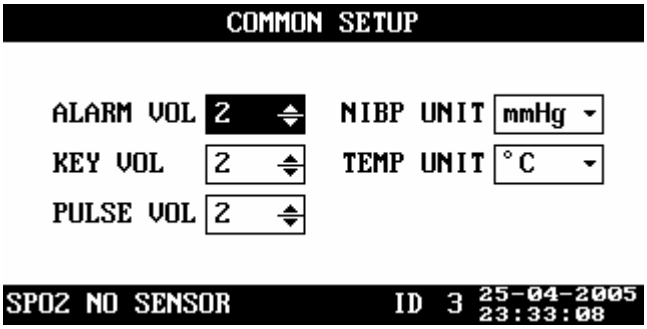

Figure 4-3

- ALARM VOL 1 - 10
- KEY VOL 0 - 10
- PULSE VOL 0 - 10
- NIBP UNIT mmHg, kPa
- TEMP UNIT ºC, ºF

The minimum alarm volume is 1 and the maximum alarm volume is 10. When the key volume or pulse volume is set to 0, it indicates that the key tone or pulse tone is disabled.

4.2.2 Default Setup

In the SYSTEM SETUP menu, select DEFAULT. The DEFAULT menu appears, as shown in the following figure.

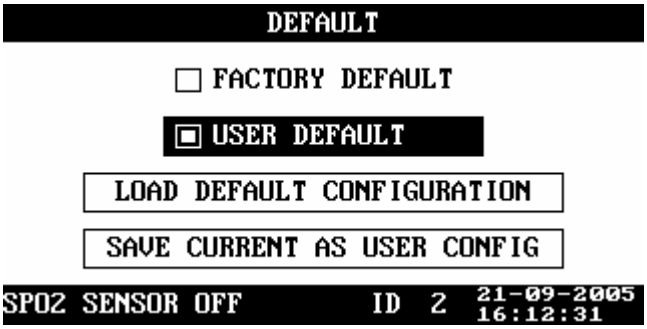

Figure 4-4

During monitoring process, you may modify some configurations as required, which, however, may not be appropriate or correct, especially for a new patient. Therefore, the DEFAULT menu is provided for you to restore the factory default configuration when necessary. In addition, you can also save the modified configuration as user default configuration.

Restoring default configuration

1. Move the cursor to FACTORY DEFAULT or USER DEFAULT.
2. Press OK to change "□" to "■".
3. Move the cursor to LOAD DEFAULT CONFIGURATION, and then press OK.
4. The CONFIRM DEFAULT CONFIG menu appears. Select YES to restore the factory default configuration or the user default configuration.

Saving as user default configuration

1. Verify the modified configuration is approriate and correct.
2. Move the cursor to SAVE CURRENT AS USER CONFIG, and then press OK.
3. The CONFIRM SAVE USER CONFIG menu appears. Select YES to confirm it.

4.2.3 Nurse Call Setup

In the SYSTEM SETUP menu, select NURSE CALL. The NURSE CALL SETUP menu appears, as shown in the following figure.

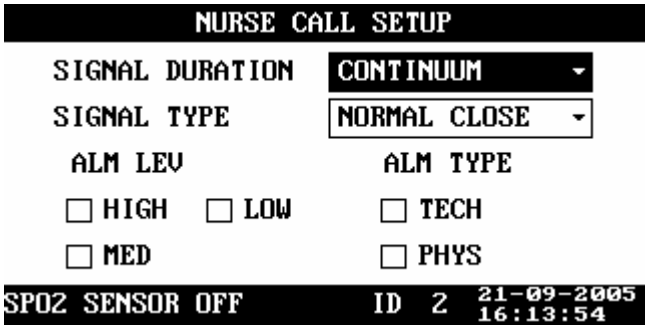

Figure 4-5

- SIGNAL DURATION

1. CONTINUUM

It indicates that the nurse call signal duration is the same with the alarm duration, namely, the nurse call signal lasts from the beginning of the alarm to the end of the alarm.

2. PULSE

It indicates that the nurse call signal is a pulse signal whose duration is 1s. When multiple alarms occur, the monitor outputs only one pulse signal; if another alarm occurs before the current alarm is cleared, the monitor will output another pulse signal.

- SIGNAL TYPE

1. NORMAL CLOSE: set the signal type to NORMAL CLOSE when the nurse call system of the hospital is set to normally-closed;
2. NORMAL OPEN: set the signal type to NORMAL OPEN when the nurse call system of the hospital is set to normally-open.

- ALM LEV: HIGH, MED, LOW; check box
- ALM TYPE: TECH, PHYS; check box.

The system will send the nurse call signal according to the selected alarm level and alarm type. If neither alarm level noralarm type is selected, the system will not send any nurse call signal when alarms occur.

⚠ CAUTION

- **Then nurse call settings shall not be changed by non-medical staff.**

NOTE

- **The medical/nursing staff are not expected to take the nurse call function as the major alarm notification. The patient conditions should be determined based on the audible/visual alarm of the monitor and the clinical symptoms of the patient.**
- **In the Alarm Paused or System Silenced status, the nurse call function will be disabled.**

4.2.4 Network Setup

In the SYSTEM SETUP menu, select NET SETUP. The NET SETUP menu appears, as shown in the following figure.

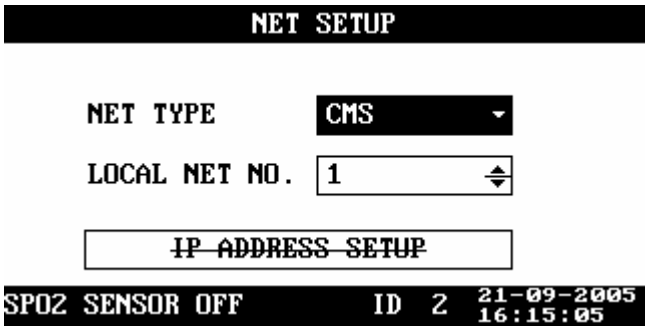

Figure 4-6

- NET TYPE: CMS, CMS+
- LOCAL NET NO.: It indicates the bed number of a monitor in the monitoring network. If the NET TYPE is CMS, the LOCAL NET NO can be set between 1 and 64; if the NET TYPE is CMS+, it can not be set.
- IP ADDRESS SETUP: When the monitor is connected with the central monitoring system, and the NET TYPE is CMS+, you need to set the IP address of your monitor .Set IP ADDDRESS SETUP in NET SETUP menu

The network type and local net No. are related to the central monitoring system (CMS) to which the monitor is connected. Contact the CMS technical personnel of Mindray or of the hospital for any doubt.

4.2.5 Data Output

To output data,

1. Ensure the monitor is connected to the PC on which the Patient Information Recall System software is running.
2. In the SYSTEM SETUP menu of the monitor, select DATA OUT, and then press OK.
3. If the connection is available, the data (including patient ID, patient type and trend data of all patients) will be output to the PC. For more information, please refer to the help information of the Patient Information Recall System software.

4.2.6 Time Setup

In the SYSTEM SETUP menu, select TIME SETUP. The TIME SETUP menu appears, as shown in the following figure.

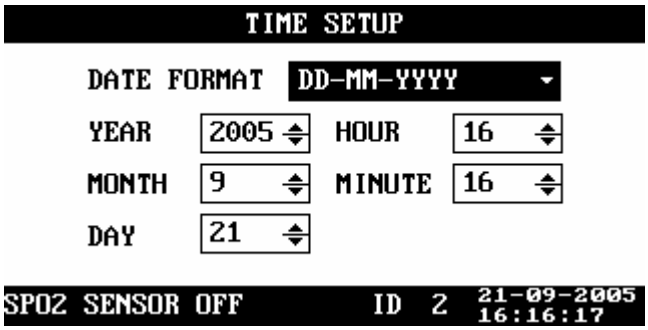

Figure 4-7

- DATE FORMAT: You can set DATE FORMAT to any of the following formats:

1. YY-MM-DD
2. MM-DD-YY
3. DD-MM-YY

Then, you can set the year, month, day, hour and minute respectively as required.

4.2.7 Version

In the SYSTEM SETUP menu, select VERSION, and then you can view the version of the monitor, as shown in the following figure.

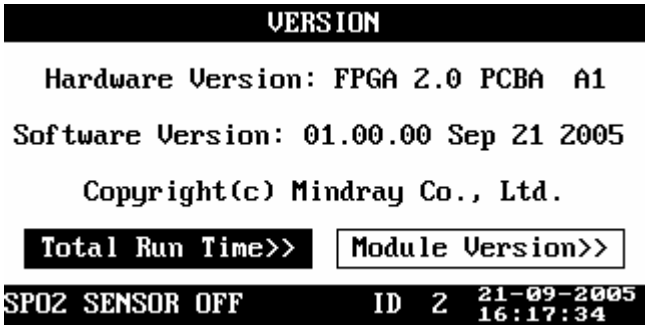

Figure 4-8

The information presented above may be different from that on your monitor. In this case, take the version information on your monitor as standard.

4.2.8 Maintenance

In the SYSTEM SETUP menu, select MAINTAIN. The MAINTAIN menu appears, as shown in the following figure.

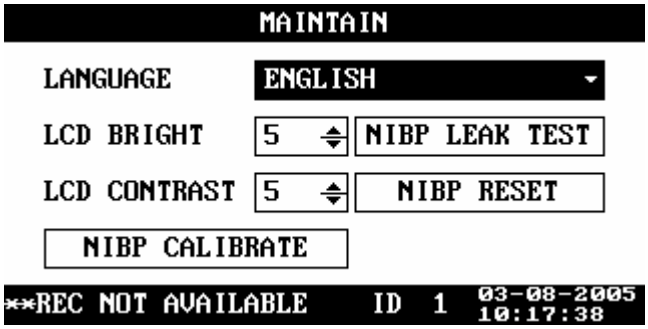

Figure 4-9

In the MAINTAIN menu, you can set

- LANGUAGE: set the language as required.
- LCD BRIGHT: 1 - 10
- LCD CONTRAST: 1 - 10
- NIBP RESET: used to reset the NIBP module;
- NIBP CALIBRAE: used to calibrate the NIBP module;
- NIBP LEAK TEST: used to test the NIBP module for air leakage.

For details about the NIBP reset, NIBP calibration and test for air leakage, refer to ***9 NIBP Monitoring***.

4.3 Alarm Setup

Press on the front panel of the monitor. The SET ALARMS menu appears, as shown in the following figure. In this menu, you can set the NIBP and SpO_2 alarm switches as well as the corresponding upper and lower alarm limits.

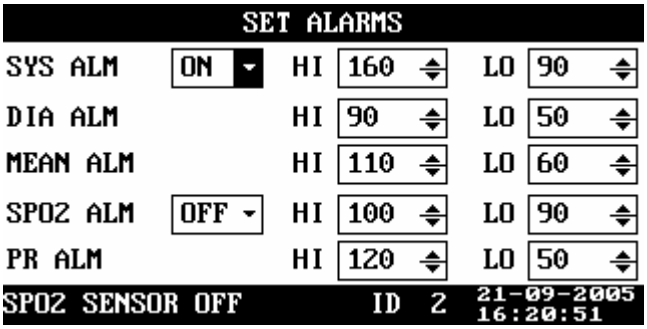

Figure 4-10

By setting the alarm switch on the right of SYS ALM to ON/OFF, you can enable or disable the physiological alarm for the NIBP measurement. By setting the alarm switch on the right of SpO_2 ALM to ON/OFF, you can enable or disable the physiological alarm for the SpO_2 measurement.

HI indicates the upper alarm limit, and LO indicates the lower alarm limit.

Move the cursor to HI/LO, and then press , and to set the upper alarm limit and lower alarm limit for each parameter.

When an NIBP value goes beyond the set upper/lower alarm limit, it will trigger the alarm. The ranges of alarm limits are listed below:

Patient type	**Adult**	**Pediatric**	**Neonate**
Systolic pressure	40 - 270 mmHg	40 - 200 mmHg	40 - 135 mmHg
Mean pressure	20 - 230 mmHg	20 - 165 mmHg	20 - 110 mmHg
Diastolic pressure	10 - 210 mmHg	10 - 150 mmHg	10 - 100 mmHg

When an SpO_2/PR value goes beyond the set upper/lower alarm limit, it will trigger the alarm. The ranges of alarm limits are listed below:

SpO_2 module type	**SpO_2**	**PR**
Mindray	0 – 100%	0 - 254 bpm
Masimo	0 - 100%	0 - 240 bpm
Nellcor	0 - 100%	0 - 250 bpm

4.4 Trend Data Screen

The trend data screen is the default screen after the start-up. It displays the systolic pressure (S), diastolic pressure (D) and mean pressure (M) of the NIBP monitoring as well as the SpO_2 and PR. As shown in the following figure.

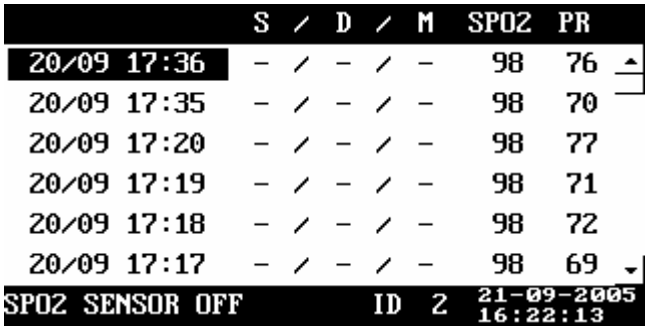

Figure 4-11

Press ▲ or ▼ to select a trend data, and then press OK. The DELETE dialog box appears. As shown in the following figure. In this dialog box, select CURRENT ITEM, ITEMS OF CURRENT ID, or ITEMS OF ALL ID and then select YES to delete the current trend data, all trend data of current ID, or data of all ID.

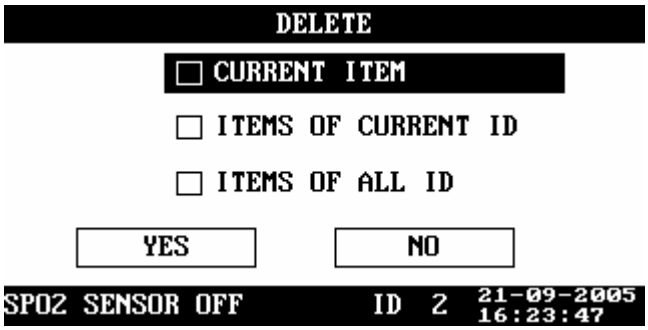

Figure 4-12

4.5 PLETH Waveform Screen

Press on the front panel of the monitor to display the PLETH waveform screen, as shown in the following figure.

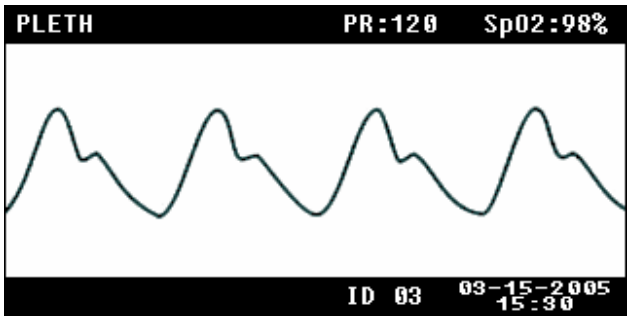

Figure 4-13

4.6 INTERVAL

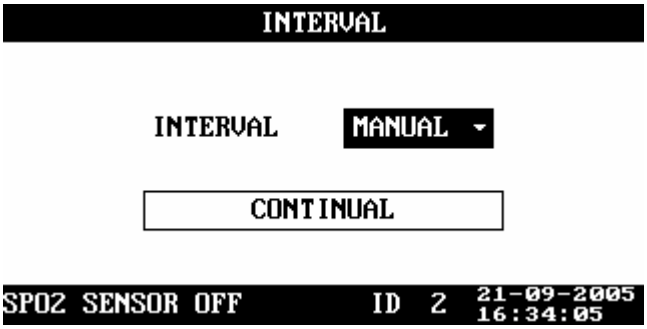

Figure 4-14

- INTERVAL: MANUAL, 1/2/3/4/5/10/15/30/60/90/120/180/240/480MIN
- CONTINUAL: The monitor performs the NIBP measurements continuously for five minutes.

Once INTERVAL is set to a value other than MANUAL, the monitor will starts an auto NIBP measurement based on the selected interval.

4.7 Standby State

4.7.1 Entering the Standby State

Press for less than 2 seconds. The CONFIRM STANDBY STATE dialog box appears prompting “Enter the Standby State. Yes?” Select YES to enter the standby state.

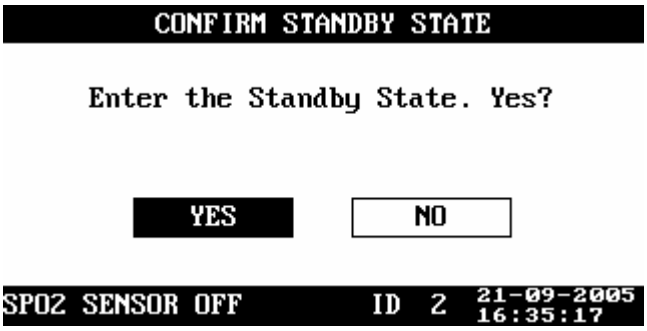

Figure 4-15

4.7.2 Exiting the Standby State

In the Standby state, press any key on the front panel of the monitor. The EXIT STANDBY dialog box appears prompting “Enter monitoring state?” Select YES to exit the Standby state and enter the monitoring state. If no operation is done within 30 seconds, the monitor will automatically select NO, this dialog box will disappear, and the monitor will keep in the Standby state.

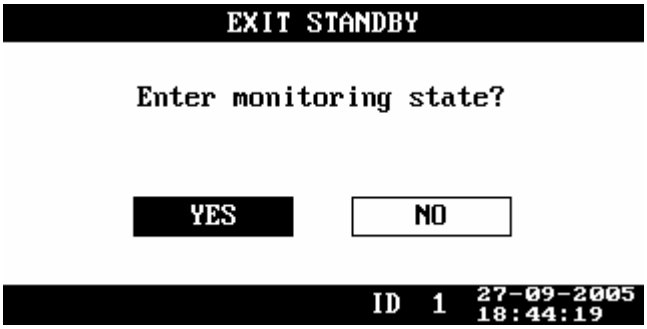

Figure 4-16

The monitor exits the standby state and enters the monitoring state automatically when

- The monitor receives SpO_2 physiological signal for 5 seconds or more.
- The probe is withdrawn from the probe sheath.
- The monitor is powered by the internal battery which is to be depleted.
- In the latter condition, the monitor prompts “BAT. VOLTAGE LOW” after entering the monitoring status.

FOR YOUR NOTES

5 Alarms

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5.1 Overview

The monitor gives audible or visual alarms to indicate the medical staff, when a vital sign of the patient appears abnormal, or mechanical or electrical problems occur to the monitor.

NOTE

- **For details about alarm setup of this monitor, please refer to 4.3 Alarm Setup.**

5.1.1 Alarm Categories

By nature, the alarms are divided into three categories: physiological alarms, technical alarms and prompt information.

1. Physiological alarms

A physiological alarm either indicates that a monitored physiological parameter goes beyond specified limits or indicates an abnormal patient condition. For example, no pulse is detected.

2. Technical alarms

A technical alarm indicates that the monitor or parts of the monitor is not capable of accurately monitoring the patient's condition due to improper operation or system failure. Technical alarms are also referred to as system error messages. For example, an error occurs in the module initialization.

3. Prompt information

Strictly speaking, prompt information cannot be counted in alarms. It is usually information relating to the system, but not concerning vital signs of patients. For example, the monitor prompts "REC INITIALIZING".

5.1.2 Alarm Levels

By severity, the alarms of this monitor are divided into three priority levels: high level alarms, medium level alarms and low level alarms.

1. High level alarms

- The patient is in danger and requires emergency treatment, or
- A serious technical problem occurs to the monitor, such as an error in the NIBP module self-test.

2. Medium level alarms

- Vital signs of the patient become abnormal, and patient requires immediate treatment, or
- A specific technical problem occurs to the monitor, such as the leakage in the NIBP hose.

3. Low level alarms

- A specific technical problem occurs to the monitor, for example, the SpO_2 signal is too weak during the measurement.

The levels of all technical alarms and some physiological alarms are not user-adjustable, because they have been fixed when the monitor is produced. All physiological alarms, technical alarms and prompt information are given in ***Appendix C Alarm Messages and Prompt .***

5.2 Alarm Modes

When an alarm occurs, the monitor raises the user's attention by the following audible or visual indications.

- Visual alarms
- Audible alarms
- Alarm messages

Besides, the visual alarms, audible alarms and alarm messages are given in different ways to identify different alarm levels.

5.2.1 Visual Alarms

The alarm indicator on the front panel of the monitor varies its flash color and frequency to indicate different alarm levels.

- High level alarm: red and quick flash.
- Medium level alarm: yellow and slow flash.
- Low level alarm: yellow light without flash.

5.2.2 Audible Alarms

The monitor uses different alarm tones to indicate different alarm levels.

- High level alarm: "DO-DO-DO--DO-DO---DO-DO-DO--DO-DO".
- Medium level alarm: "DO-DO-DO".
- Low level alarm: "DO".

Different intervals correspond to different alarm levels: High level alarm phonates once every 3 or 8 seconds. Medium level alarm phonates once every 14 or 24 seconds. Low level alarm phonates once every 24 seconds.

5.2.3 Alarm Messages

Alarm messages are given when alarms occur. The alarm messages are displayed in the physiological alarms area or the technical alarms area in black. For physiological alarms, asterisks are displayed before the alarm messages to identify the alarm level.

- High level alarms: triple asterisks "***"
- Medium level alarms: dual asterisks "**"
- Low level alarms: single asterisk "*"

5.3 Alarm Status

When an alarm occurs, normally the monitor gives indications in the modes mentioned above as per the alam level. If necessary, you can set the monitor to the following alarm status.

- Alarms Disabled
- Alarms Paused
- System Silenced

5.3.1 Alarms Disabled

If the alarm switch of a parmater is set to OFF, the monitor does not generate alarms even if the measured parameter value exceeds the alarm limit. This status is called Alarms Disabled.

To disable the alarms of a parameter, you need to open SET ALARMS menu .Take NIBP (Non-Invasive Blood Pressure) as an example.

1. Press to open the SET ALARMS menu.
2. Move the cursor to the pane to the right of SYS ALM.
3. Press , and then press or .
4. Select OFF, and press to disable the alarm switch for the NIBP parameter.

5.3.2 Alarms Paused

To suspend all alarms of the monitor, the duration of the alarm pause is fixed to 2 minutes, press on the front panel once (for less than 2 seconds). In Alarms Paused status,

- Visual alarms and audible alarms are all suspended.
- Alarm messages are not displayed.
- The alarm message area shows the rest time of alarms paused status.

When the alarms paused time expires or a new technical or physiological alarm occurs within the Alarms Paused time, the monitor will terminate the Paused Alarm status and return to normal status. Besides, you can also manually termiante the Alarms Paused status by pressing once.

5.3.3 System Silenced

To silence the system, press for 2 seconds or more. In the System Silenced status, all system sounds are shielded. However, other modes of alarms (excluding audible alarms) are given as normal. A new technical or physiological alarm will terminate the System Silenced status. The system sounds include the audible alarms, key tones and pulse tones.

5.3.4 Status Switchover

In the Normal status,

- Press for less than 2 seconds to switch the monitor to the Alarms Paused status, or
- Press for 2 seconds or more to switch the monitor to the System Silenced status.

In the Alarms Paused statuses,

- Press for less than 2 seconds to switch the monitor to the Normal status, or
- Press for 2 seconds or more to switch the monitor to the System Silenced status.
- When the Alarm Paused time expires, the system will automatically switch to the Normal status.
- Within the Alarm Paused time, when a new technical or physiological alarm occurs, the system will automatically switch to the Normal status.

In the System Silenced status,

- Press for less than 2 seconds to switch the monitor to the Alarms Paused status, or
- Press for 2 seconds or more to switch the monitor to the Normal status.
- When a new technical/physiological alarm occurs, the system will automatically switch to the Normal status.

5.4 Clearing Alarms

1. Clearing audible and visual alarm indications

For a specific technical alarm, the audible and visual alarm indications will be cleared if the monitor is set to the Alarms Paused status (by pressing for less than 2 seconds) and the alarm message will be changed to prompt information during and after the alarms paused time. If the technical alarm is triggered again after the monitor restores to the normal status, the monitor will give alarm indications as normal.

For technical alarms whose audible and visual indications can be cleared, refer to ***Appendix C Alarm Messages and Prompt*** .

2. Clearing all alarm indications

For a specific technical alarm, if the monitor is set to the Alarms Paused status (by pressing for less than 2 seconds), all alarm indications will be cleared during and after the alarms paused time. If the technical alarm is triggered again after the monitor restores to the normal status, the monitor gives alarm indications as normal.

5.5 When an Alarm Occurs

⚠WARNING

- **When an alarm occurs, always check the patient's condition first.**

When an alarm occurs to the monitor, refer to the following steps and take action properly.

1. Check the patient's condition.
2. Identify the alarming parameter and the alarm category.
3. Identify the cause of the alarm.
4. Take action to remedy the alarm cause.
5. Check if the alarm is cleared.

NOTE

- **For details about how to deal with specific alarms, refer to *Appendix C Alarm Messages and Prompt* .**

FOR YOUR NOTES

6 Recording

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6.2 Recorder Operations 6-2
6.3 Installing Recorder Paper 6-3

6.1 Overview

A thermal recorder is to be installed on the left side panel of the monitor. The recorder is capable of printing:

- Real-time PLETH waveforms.
- Current displayed trend data.
- All trend data of the current patient.

6.2 Recorder Operations

To print a real-time PLETH waveform

1. Press to open the PLETH waveform screen.
2. Press for less than 2 seconds to print the current displayed PLETH waveform.

To print current displayed trend data

1. Enter the trend data screen.
2. Press for less than 2 seconds to print the current displayed trend data.

To print all trend data of the current patient

1. Enter the trend data screen.
2. Press for 2 seconds or more to print all trend data of the current patient.

NOTE

- **You can stop the printing at any time by pressing .**
- **For the recorder status information and the corresponding handling measures, refer to Appendix C Alarm Messages and Prompt .**

6.3 Installing Recorder Paper

Installing Procedure

1. Press the latch at the upper right of the paper compartment door to release the door.
2. Lift the roller lever located at the upper left of the paper compartment, as shown in the following figure.
3. Install a new roll of recorder paper into the compartment, as shown in the following figure.
4. The roller of the recorder scrolls automatically, and the paper comes out of the compartment.
5. Push down the roller lever.
6. Close the recorder door.

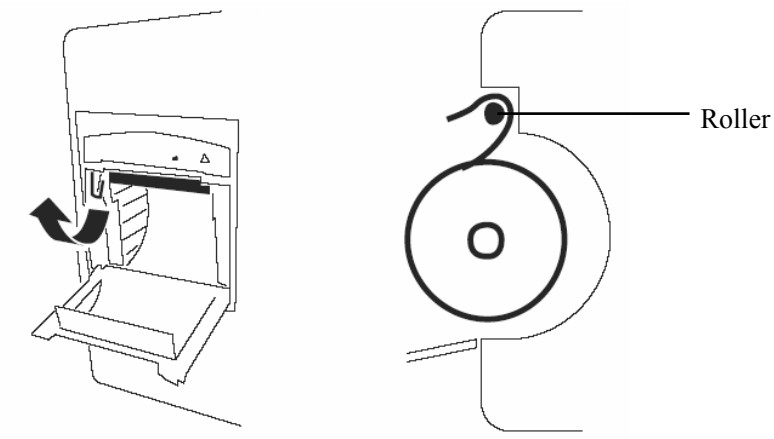

Figure 6-1 Installing Recorder Paper

⚠CAUTION

- **Use the thermal recorder paper specified by Mindray only. Other recorder paper may cause the recorder to print with poor quality, function improperly or not at all, or bring damage to the thermal print head.**
- **Do not pull the recorder paper with force when the printing is in process. Otherwise, damages to the recorder may be incurred.**
- **Do not leave the recorder door open except when you are replacing the recorder paper or removing a fault.**

Removing the Paper Jam

If the recorder does not function properly or produces unusual sound, check whether there is a paper jam. If yes, remove it in the following procedure:

1. Open the recorder door.
2. Tear the paper off from the leading edge at the paper outlet.
3. Lift the lever on the upper left of the recorder.
4. Pull the paper from the paper inlet.
5. Re-install the paper.

7 Management System Software

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The Prsview management system software (PV software as referred to hereinafter) is optional for the VS-800 Vital Signs Monitor. It is used in conjuction with the VS-800 system software and implements the following functions:

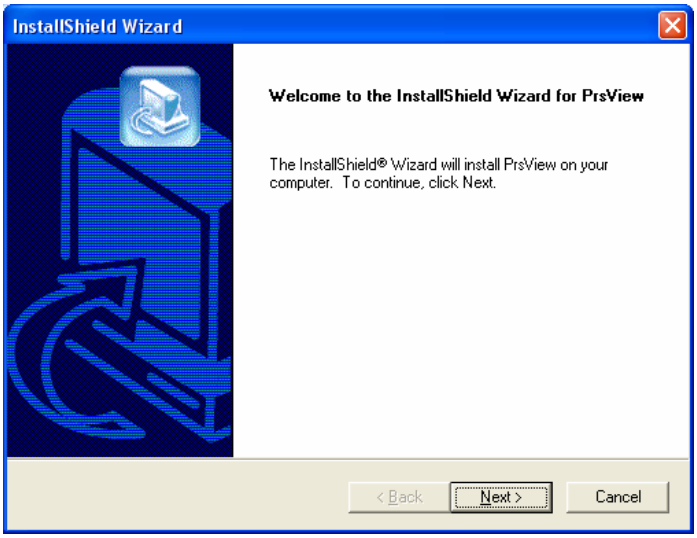
- Data output and software upgrade.
- Display of output data.
- Addition/modification of patient information.
- Data printing.

7.1 Installation and Uninstallation

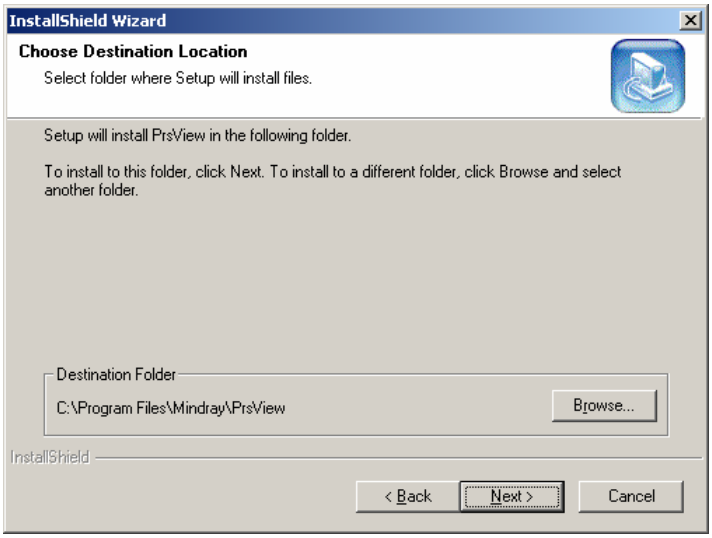
7.1.1 Installing the PV Software

The PV software supports Windows 98/2000/XP operating system (Chinese/English Edition). In this operation manual, the installation of the PV software is introduced with an example of installation under the Windows 2000 operating system.

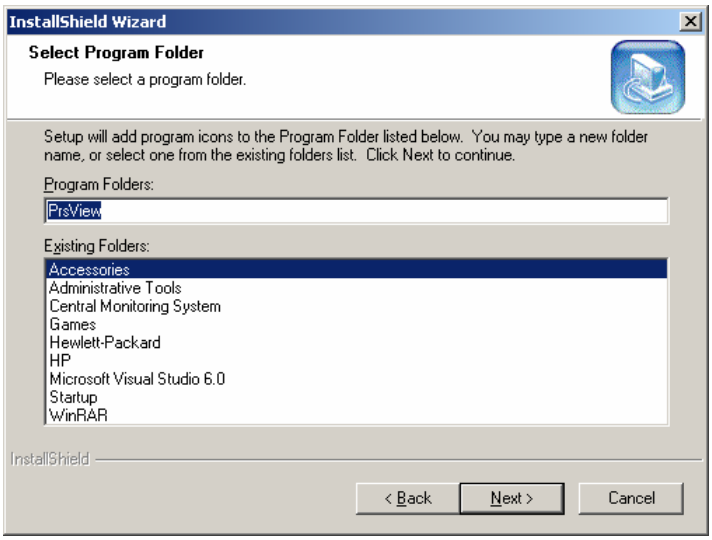
1. Insert the installation disk into the CD driver.
2. Run the Setup.exe file in the installation disk. Then the following dialog box appears.


InstallShield Wizard
Welcome to the InstallShield Wizard for PrsView
The InstallShield® Wizard will install PrsView on your computer. To continue, click Next.
< Back
Next >
Cancel

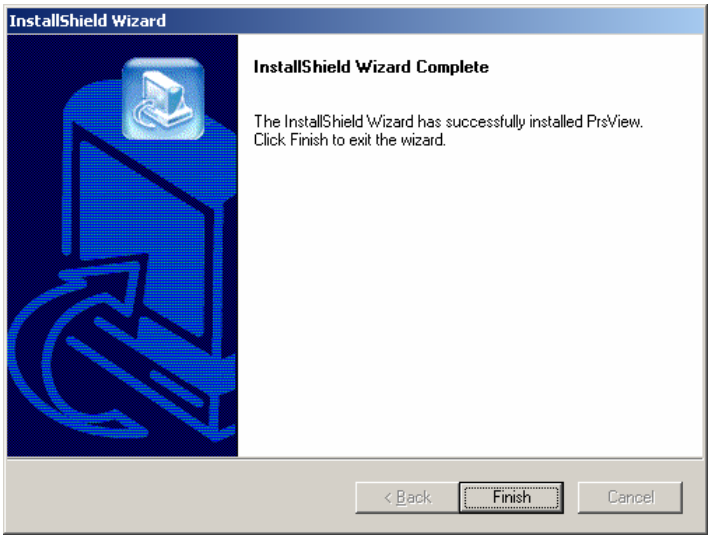
3. In this dialog box, click Next. Then the following dialog box appears.


InstallShield Wizard
Choose Destination Location
Select folder where Setup will install files.
Setup will install PrsView in the following folder.
To install to this folder, click Next. To install to a different folder, click Browse and select another folder.
Destination Folder
C:\Program Files\Mindray\PrsView
Browse...
InstallShield
< Back
Next >
Cancel

4. In this dialog box, click Next. Then the following dialog box appears.



5 Click Finish.



Once the installation is finished, a PrsView short-cut icon will appear on the desktop, and the shortcut will appear in the **Start** menu.

7.1.2 Uninstalling the PV Software

To uninstall the PV software, follow the procedure below:

1. Click the Start menu, and select Control Panel-Add/Delete Program.
2. In the Add/Delete Program dialog box, select PrsView, and then click Delete to uninstall the PV software.

Note

- **The procedures above are for reference only. The installation or uninstallation procedures may different in different operating systems.**

7.1.3 Network Connection

Before operation, you need to connect the PC and the monitor with a cross-type network cable, then run the Prsview software.
In the SYSTEM SETUP menu of the monitor, select NET SETUP, and then set NET TYPE to CMS or CMS+.

- For CMS, set the IP address of the PC to 202.114.4.119.
- For CMS+, set the IP address of the PC to a value among where the first three domains are the same with that of the IP address of the monitor and the last domain is different from that of the IP address of the monitor.

7.2 Main Window

Click the PV software in the **Start** menu. The main window shown in the following figure appears.

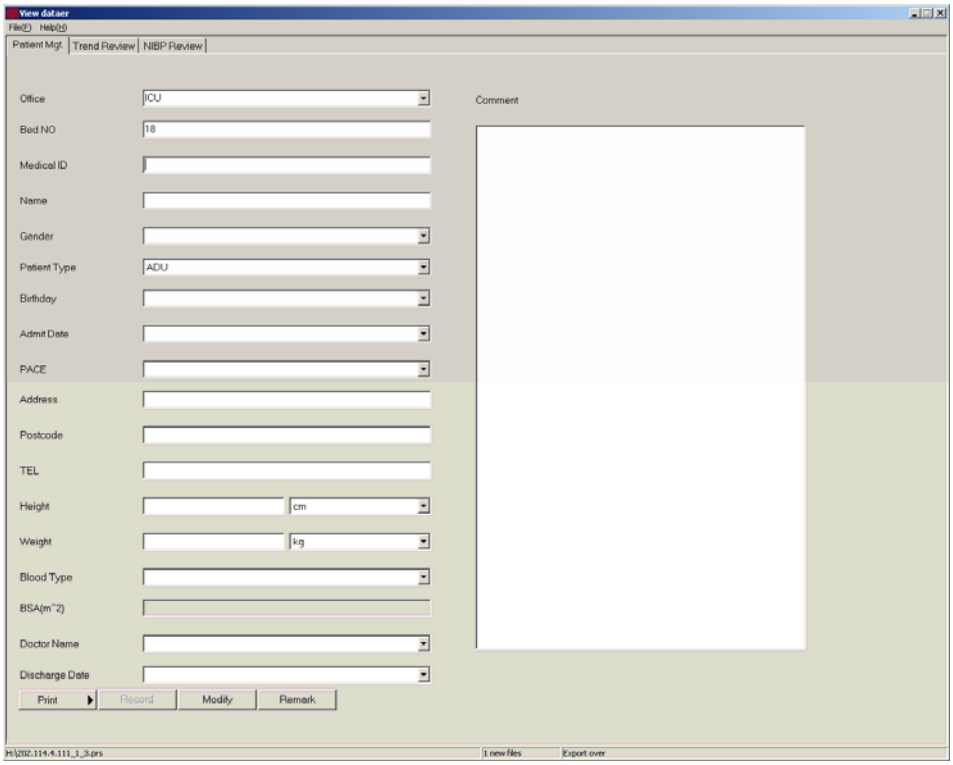
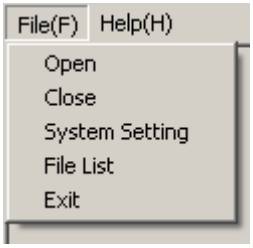


Figure 7-1

7.2.1 Menu Bar

Click **File** in the menu bar. The **File** pull-down menu appears, as shown in the following figure.



- Open: to open thefile dialog box.
- Close: to close the file dialog box.
- System setting: to modify the color and unit of the module, as shown in Figure 7-1

- File List: same as Open.
- Exit: to exit the current application.

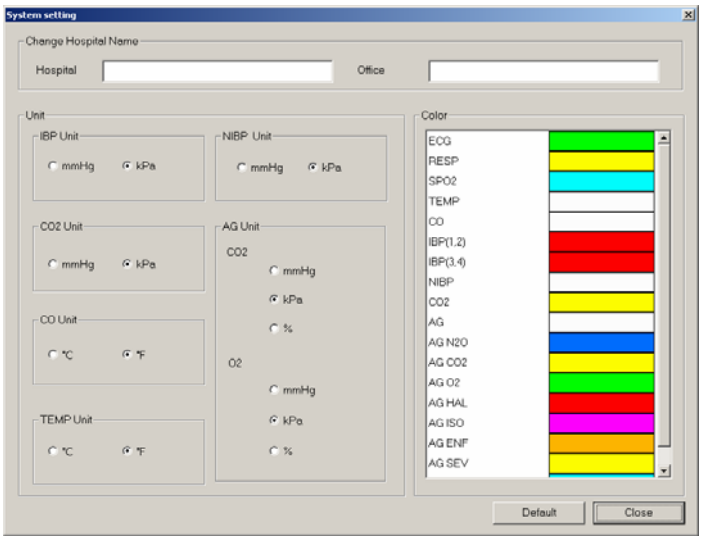


Figure 7-1

7.2.2 Patient Management

In the **Patient Management** tab, you can enter the following information:

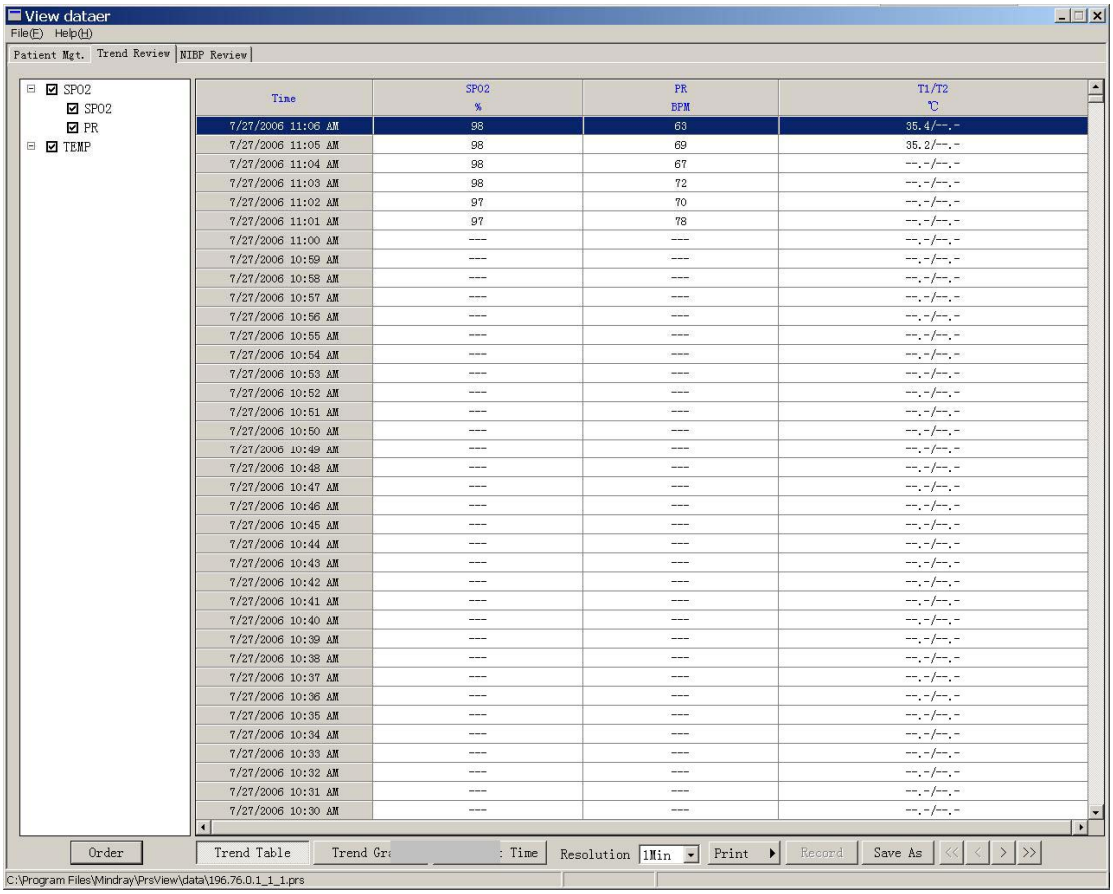
- Department: to be selected from the drop-down list box.
- Bed No.: to be entered; Range: 1 – 99.
- Patient No.: composed of English letters and/or numerals, maximum characters: 12.
- Name: up to 12 characters for English letters, or up to 12 Chinese characters.
- Sex: male or female.
- Patient Type: to be selected from the drop-down list box.
- Birthday: to be selected from the drop-down list box.
- Admit Date: to be selected from the drop-down list box.
- Pace: to be selected from the drop-down list box.
- Address: patient address, to be entered.
- Post Code: up to 12 numerals can be entered.
- Telephone: up to 24 numerals can be entered.
- Height: to be entered per either of the two optional units.
- Weight: to be entered per either of the two optional units.
- Blood Type: to be selected from the drop-down list box.

- Body Surface Area: to be obtained and displayed automatically based on the entered height and weight.
- Doctor: up to 12 characters for English letters, or up to 12 Chinese characters.
- Discharge Date: to be selected from the drop-down list box.
- Diagnosis: Result: to be entered by doctor.
- Print: the patient data within the set ID range can be printed.
- Record: to record data.
- Modify: to save the currently set information.
- Additional: to supplement patient information.

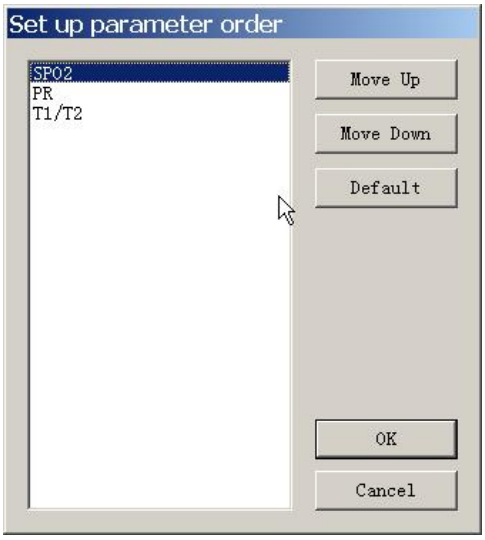
7.3 Software Functions

7.3.1 Trend Review

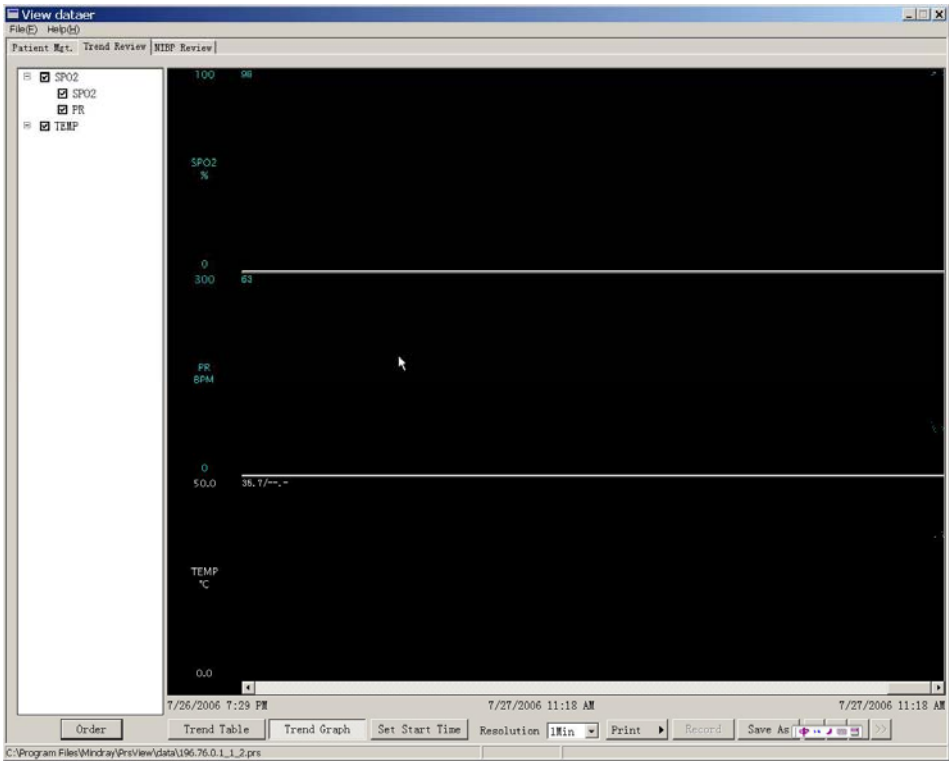
In the Main Window, select the **Trend Review** tab. The SpO_2 and PR data can be reviewed in the **Trend Review** tab, as shown in the following figure:



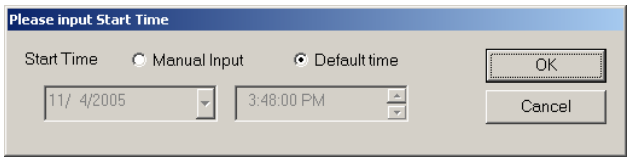
- Order: to enter the Set up parameter order dialog box. See the following figure.



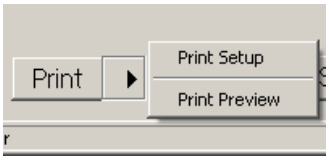
- Trend Graph: to display the SpO_2 and PR data, see the following figure.



- Set Start Time: to enter the Please input Start Time dialog box, see the following figure.



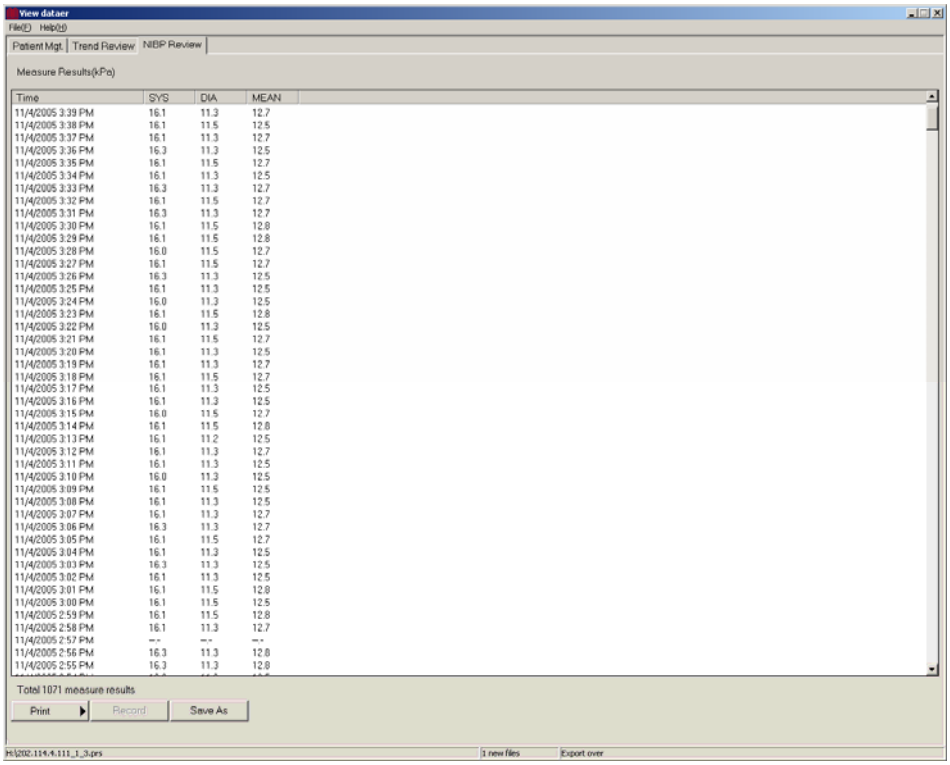
- Resolution to select the resolution from the drop-down list box. Options: 1Min, 5Min, 15Min, 30Min and 60Min.
- Print: to print data directly or to access Print Setup or Print Preview by clicking the arrow on the right of the Print button. See the following figure.



- Save As: to save data into a file.

7.3.2 NIBP Review

In the Main Window, select the **NIBP Review** tab. The measured NIBP results can be reviewed in the **NIBP Review** tab, as shown in the following figure.



8 SpO_2 Monitoring

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This monitor can be equipped with any of the following SpO_2 modules:

- Mindray SpO_2 module
- Masimo SpO_2 module
- Nellcor SpO_2 module.

A monitor, equipped with a Masimo or Nellcor SpO_2 module, is marked by "Masimo" or "Nellcor" at the lower left corner of the front panel. The following pages respectively gives introduction to the above three SpO_2 modules. Please read this chapter according to your monitor configuration before operation.

8.1 Mindray SpO_2 Module

NOTE

- **This section is only applicable to the monitor equipped with a Mindray SpO_2 module.**

8.1.1 Principles of Operation

The oxygen saturation (SpO_2) is measured with a method called pulse oximetry. It is a continuous, non-invasive method based on the different absorption spectra of reduced hemoglobin and oxyhemoglobin. It measures how much light, sent from light sources on one side of the sensor, is transmitted through patient tissue (such as a finger or an ear), to a receiver on the other side. The amount of light transmitted depends on many factors, most of which are constant. However, one of these factors, the blood flow in the arteries, varies with time regularly, because it is pulsating. By measuring the light absorption during a pulsation, it is possible to calculate the oxygen saturation of the arterial blood. Detecting the pulsation gives a PLETH waveform and pulse rate value.

The sensor measurement wavelengths are nominally 660nm for the red LED and 940nm for infrared LED. The maximum optical power output for LED is 4 mW.

8.1.2 Precautions

⚠WARNING

- **The SpO_2 value can be overestimated in the presence of Hb-CO, Met-Hb or dye dilution chemicals.**
- **Check if the sensor is in normal condition before monitoring. Do not use the SpO_2 sensor once the package or the sensor is found damaged.**
- **After unplugging the SpO_2 sensor cable from the connector of the monitor, the system shall display the alarm message "SPO2 SENSOR OFF" and give the audible alarm.**

- **ES (Electrosurgery) equipment wire and SpO_2 cable must not be tangled up.**
- **Do not put the SPO_2 sensor on extremities with arterial catheter or venous syringe.**
- **Do not perform SpO_2 monitoring and NIBP measurements on the same limb simultaneously. Obstruction of blood flow during NIBP measurements may adversely affect the SpO_2 reading.**
- **During prolonged and continuous monitoring, check the sensor placement regularly to ensure proper attachment, and move to another location if the skin deteriorates. More frequent examinations may be required for different patients, like neonates and patients of poor perfusion or skin sensitive to light.**

NOTE

- **SpO_2 waveform is not proportional to the pulse volume.**

8.1.3 Monitoring Procedure

Sensor selection for the SpO_2 measurement depends on the patient type. For an adult patient, you can choose a finger SpO_2 sensor; for an infant patient, you can choose a hand or toe sensor. Perform SpO_2 measurements in the following procedure.

1. Power on the monitor.
2. Attach the sensor to the proper site on the patient.
3. Plug the connector of the sensor extension cable into the SpO_2 connector on the monitor.

Finger Sensor Placement

You can easily place the finger sensor as shown below.

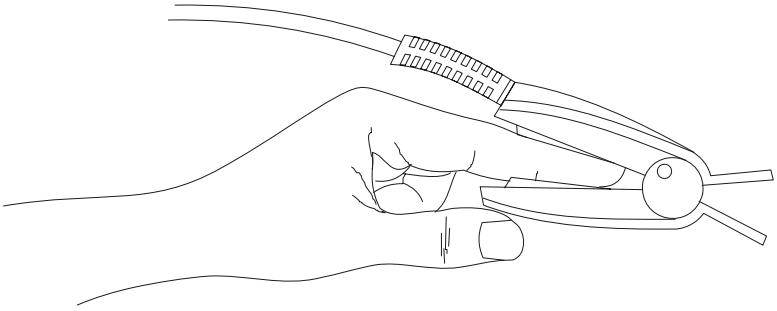


Figure 8-1 Finger Sensor Placement

NOTE

- **Place the SpO_2 sensor cable at the backside of the patient hand. Make sure the fingernail is just opposite to the light emitted from the sensor.**

Neonate Sensor Placement

Neonate SpO_2 sensor consists of a Y-shape SpO_2 sensor and its sheath. Insert the LED and PD ends of the Y-shape SpO_2 sensor respectively into the upper and lower grooves on the sheath (See Figure 8-2). Figure 8-3 shows the neonate SpO_2 sensor after inserted.

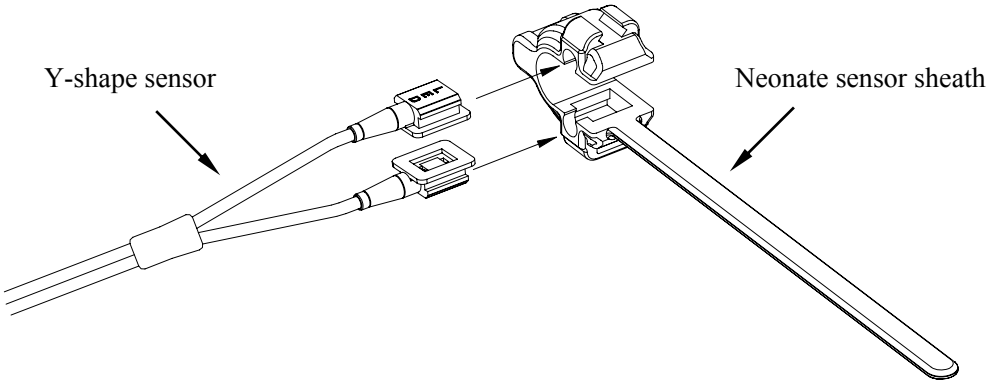


Figure 8-2 Neonate Sensor Placement (1)

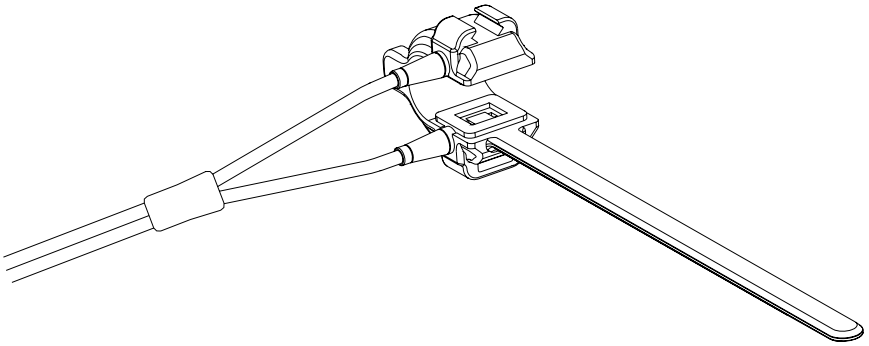


Figure 8-3 Neonate Sensor Placement (2)

Wind the SpO_2 sensor around the hand or foot of a neonate patient. Hold the sensor, pull the belt and fit one of its sides with "V" edge into the "V" groove on the corresponding side of the sheath. Appropriately elongate the belt to about 20mm, and fit the "V" edge of the other side of the belt into the "V" groove of the other side of the sheath. Then, loosen the belt. After the "V" edges of the two sides of the belt fit well into the "V" grooves on the two sides of the sheath, put the belt into the first lock bar to fasten the belt. See the following figure. If the belt is too long, you may put it into the second lock bar. You must position the SpO_2 sensor in this way so as to make the photoelectric component face the correct position. Besides, remember not to elongate the belt too much, which may lead to inaccurate measurement and block the blood circulation severely.

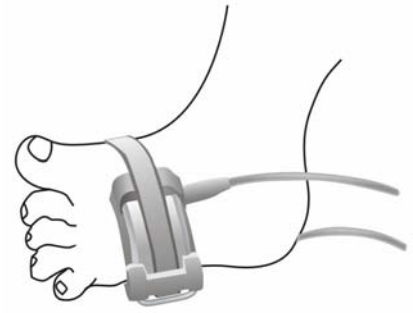


Figure 8-4 Neonate Sensor Placement (3)

NOTE

- **If the sensor cannot be positioned accurately to the part to be measured, it may result in inaccurate SpO_2 reading, or the SpO_2 even cannot be measured because no pulse is detected. In this case, you must position the sensor again.**
- **Excessive patient movements may result in inaccurate readings. In this case, you must keep the patient quiet or change the measured position to reduce the adverse influence of excessive movement.**

⚠WARNING

- **In the process of extended and continuous monitoring, you should check the peripheral circulation and the skin every 2 hours. If any unfavorable change takes place, you should change the measured position in time.**
- **In the process of extended and continuous monitoring, you should periodically check the position of the sensor. In case that the position of the sensor moves during monitoring, the measurement accuracy may be affected.**

8.1.4 Measurement Limitations

If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs with an alternate method, and then check the monitor and the sensor.

Inaccurate measurements may be caused by:

- Incorrect sensor application or use.
- High-frequency electrical noise, including the noise generated by the monitor, or the noise from external sources, such as electrosurgical apparatus connected to the system.
- Oximeters and oximetry sensors used during magnetic resonance imaging (MRI) scanning (Induced current may cause burns).
- Intravascular dye injections.

- Excessive patient motion.
- Excessive ambient light.
- Improper sensor installation or incorrect sensor placement on the patient.
- Sensor temperature (optimal temperature range: 28℃ - 42℃) when exceeded.
- The factor that the sensor is placed on a limb that is attached to an NIBP cuff, arterial catheter, or intravascular line.
- Concentration of dysfunctional hemoglobin, such as carboxyhemoglobin (COHb) and methemoglobin (MetHb).
- SpO_2 too low.
- Low circular perfusion of the applied part.
- Shock, anemia, low temperature and application of vasomotor which reduce the arterial blood flow to such a degree that the SpO_2 measurement cannot be performed.

The absorption of oxyhemoglobin (HbO_2) and deoxyhemoglobin to the light of special wavelength may also affect the accuracy of the SpO_2 measurement. If there are other substances (such as carbon hemoglobin, methemoglobin, methylene blue and indigo carmine) absorbing the light of the same wavelengths, they may result in false or low SpO_2 readings.

8.2 Masimo SpO_2 Module

NOTE

- **This section is only applicable to the monitor equipped with a Masimo SpO_2 module.**

8.2.1 Principles of Operation

The pulse oximetry measurement module (Masimo Set) is based on three principles:

- Oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry).
- The volume of arterial blood in tissue and the light absorbed by the blood changes during the pulse (plethysmography).
- Arterio-venous shunting is highly variable, and the fluctuating absorbance by venous blood is a major component of noise during the pulse.

The working principle of Masimo Set uses is similar to the traditional SpO_2 module. It calculates the SpO_2 value by passing red and infrared light into a capillary bed and measuring changes in light absorption during the pulsatile cycle. The red and infrared light-emitting diodes (LEDs) in oximetry sensors serve as the light sources, and the photodiode serves as the photodetector.

Traditional pulse oximeter assumes that all pulsations in the light absorbance signal are caused by oscillations in the arterial blood volume. This assumes that the blood flow in the region of the sensor passes entirely through the capillary bed rather than through any arterio-venous shunts. The traditional pulse oximeter calculates the ratio of pulsatile absorbance (AC) to the mean absorbance (DC) at each of two wavelengths, 660 nm and 940 nm:

$$\mathrm{Re}d(660) = AC(660)/DC(660)$$

$$Ir(940) = AC(940)/DC(940)$$

This traditional instrument then calculates the ratio of these two arterial pulse-added absorbance signals:

$$R = \mathrm{Re}d(660)/Ir(940)$$

This value of R is used to find the SpO_2 in a look-up table built into the instrument's

software. The values in the look-up table are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia studies.

This Masimo Set assumes that arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is the major component of noise during the pulse. The Masimo Set decomposes S (660) and S (940) into an arterial signal plus a noise component and calculates the ratio of the arterial signals without the noise:

$$\mathrm{Re}\,d(660) = Sr + Nr$$

$$Ir(940) = Si + Ni$$

$$R = Sr / Si$$

Again, R is the ratio of two arterial pulse-added absorbance signals and its value is used to find the saturation SpO_2 in an empirically derived equation into the software. The values in the empirically derived equation are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia studies.

The above equations are combined and a noise reference (N') is determined:

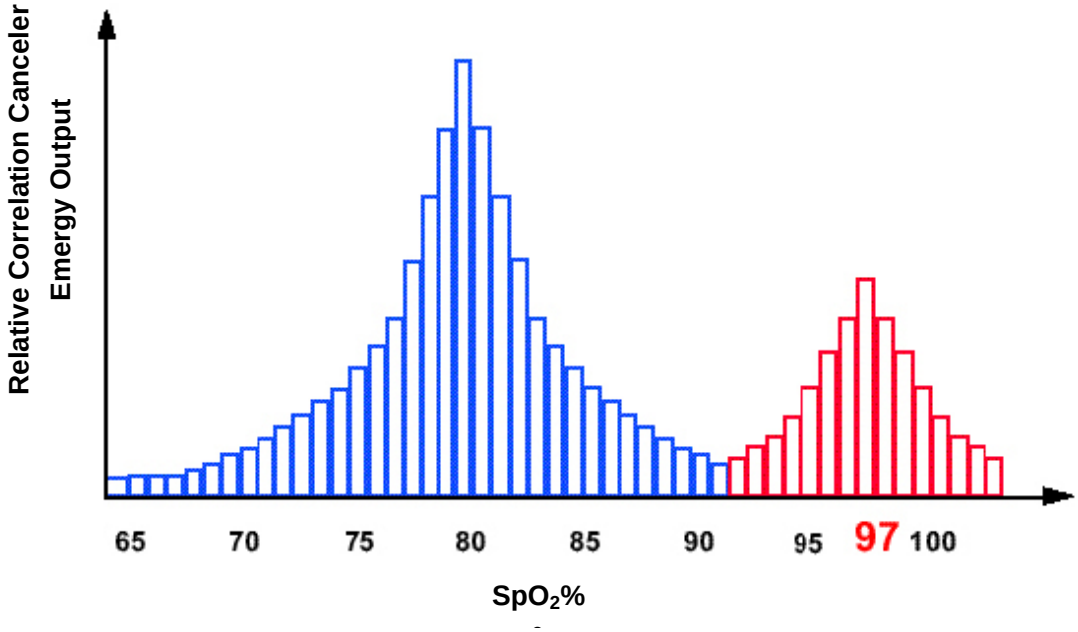
$$N' = \mathrm{Re}\,d(660) - Ir(940) \times R$$

When the noise reference (N') is 0,

$$\mathrm{Re}\,d(660) = Ir(940) \times R$$

The equation for the noise reference is based on the value of R, the value being seeked to determine the SpO_2. The Masimo Set's software sweeps through possible values of R that corresponds to SpO_2 values between 1% and 100% and generates an N' value for each of these R values. The S (660) and S (940) signals are processed with each possible N' noise reference through an adaptive correlation canceler (ACC) which yields an output power for each possible value of R (i.e., each possible SpO_2 from 1% to 100%). The result is a Discrete Saturation Transform (DST™) plot of relative output power versus possible SpO_2 value as shown in the following figure where R corresponds to SpO_2 = 97%:

Discrete Saturation Transform DST™



The DST plot has two peaks: the peak corresponding to the higher saturation is selected as the SpO_2 value. This entire sequence is repeated once every two seconds on the most recent four seconds of raw data. The SpO_2 value therefore corresponds to a running average of arterial hemoglobin saturation that is updated every two seconds.

8.2.2 Precautions

⚠WARNING

- **The pulse wave from the Masimo Set SpO_2 module should NOT be used for apnea monitoring.**
- **As a trend towards patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.**
- **Once an alarm has occurred, the system will resume the sound of the silenced alarms (except for the special cases listed in this manual).**
- **Measure the monitor's leakage current whenever an external device is connected to the serial port. Leakage current must not exceed 100 microamperes.**
- **To ensure patient electrical isolation, connect only to other equipment with electronically isolated circuits.**
- **Do not connect to an electrical outlet controlled by a wall switch or dimmer.**
- **Carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.**
- **Interfering Substances: Carboxyhemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.**
- **Do not use this instrument and the sensors during magnetic resonance imaging (MRI). Induced current could potentially cause burns. The monitor may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.**
- **The SpO_2 value might be overestimated in the presence of Hb-CO, Met-Hb or dye dilution chemicals.**
- **Verify sensor cable fault detection before beginning monitoring. Unplug the SpO_2 sensor cable from the connector. The screen displays the error message "SPO2 SENSOR OFF" and the audible alarm is activated.**
- **Do not use the supplied sterile SpO_2 sensors if the packaging or the**

sensor is damaged. Return them to the vendor.

- **Do not perform SpO_2 and NIBP measurements on the same limb simultaneously. Obstruction of blood flow during NIBP measurements may adversely affect the reading of the SpO_2 value.**
- **Prolonged and continuous monitoring may increase the risk of burns at the site of the sensor. It is especially important to check the sensor placement, and ensure proper attachment on neonates and patients of poor perfusion or skin sensitive to light. Check the sensor location every 2–3 hours and move it to another location if the skin deteriorates. More frequent examinations may be required for different patients.**

NOTE

- **Place the SpO_2 sensor cable at the backside of the patient hand. Make sure the patient nail is just opposite to the light emitted from the sensor.**
- **The SpO_2 value is not proportional to the pulse rate.**

8.2.3 Monitoring Procedure

Follow the procedure below:

1. Power on the monitor.
2. Attach the sensor to the proper site on the patient.
3. Plug the connector of the sensor extension cable into the SpO_2 connector on monitor.

The process of SpO_2 plethysmogram measurement is generally the same. But the SpO_2 sensor selection and placement depend on the patient type. When choosing a site for a sensor, refer to the directions for that sensor.

8.2.4 Measurement Limitations

If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by an alternate method and then check the monitor and the sensor.
Inaccurate measurements may be caused by:

- incorrect sensor application or use.

- significant levels of dysfunctional hemoglobins (e.g., carboxyhemoglobin or methemoglobin).
- intravascular dyes such as indocyanine green or methylene blue.
- exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight (exposure to excessive illumination can be corrected by covering the sensor with a dark material).
- excessive patient motion.
- venous pulsations.
- placement of a sensor on the same extremity with a blood pressure cuff, arterial catheter, or intravascular line.
- application during defibrillation, when, however, the readings may take a short period of time to return to normal.

Loss of pulse signal can occur when

- the sensor is too tight.
- there is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight.
- a blood pressure cuff is inflated on the same extremity as the one with an SpO_2 sensor attached.
- the patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
- there is arterial occlusion proximal to the sensor.
- the patient is in cardiac arrest or is in shock.

8.2.5 Masimo Information

The MASIMO SET® Product

Masimo Patents

This device is covered under one or more of the following U.S. Patents: 5,482,036; 5,490,505; 5,632,272; 5,685,299; 5,758,644; 5,769,785; 6,002,952; 6,036,642; 6,067,462; 6,206,830; 6,157,850 and international equivalents. U.S.A and international patents pending.

No Implied License

Possession or purchase of this device does not convey any express or implied license to use the device with replacement parts which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.

8.3 Nellcor SpO_2 Module

NOTE

- **This section is only applicable to the monitor equipped with a Nellcor SpO_2 module.**

8.3.1 Principles of Operation

Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The monitor uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying a sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photodetector. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO_2).

■ Oximetry Overview

Pulse oximetry is based on two principles:

1. Oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (i.e., spectrophotometry).
2. The volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (i.e., plethysmography).

A monitor determines SpO_2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LEDs) in the oximetry sensor serve as light sources; a photodiode serves as the photo detector.

Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of arterial hemoglobin, the monitor uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The monitor bases its SpO_2 measurements on the difference between maximum and minimum absorption (i.e., measurements at systole and diastole). By doing so, it focuses on

light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

■ Automatic Calibration

Because light absorption by hemoglobin is wavelength dependent and because the mean wavelength of LEDs varies, a monitor must know the mean wavelength of the sensor's red LED to accurately measure SpO_2. During manufacturing, the mean wavelength of the red LED is encoded in a resistor in the sensor. During monitoring, the monitor reads this resistor and selects coefficients that are appropriate for the wavelength of that sensor's red LED; these coefficients are then used to determine SpO_2.

This resistor is read when the monitor is turned on, periodically thereafter, and each time a new sensor is connected. Additionally, to compensate for differences in tissue thickness, the intensity of the sensor's LEDs are adjusted automatically.

■ Functional versus Fractional Saturation

This monitor measures functional saturation — oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen. It does not detect significant amounts of dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin. In contrast, some instruments report fractional saturation — oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobins. To compare functional saturation measurements to those from an instrument that measures fractional saturation, fractional measurements must be converted as follows:

$$\text{functional saturation} = \frac{\text{fractional}}{100 - (\%\text{carboxyhemoglobin} + \%\text{methemoglobin})} \times 100$$

■ Measured versus Calculated Saturation

When saturation is calculated from a blood gas partial pressure of oxygen (PO_2), the calculated value may differ from the SpO_2 measurement of a monitor. This usually occurs because the calculated saturation was not appropriately corrected for the effects of variables that shift the relationship between PO_2 and saturation (Figure 8-5): pH, temperature, the partial pressure of carbon dioxide (PCO_2), 2,3-DPG, and fetal hemoglobin.

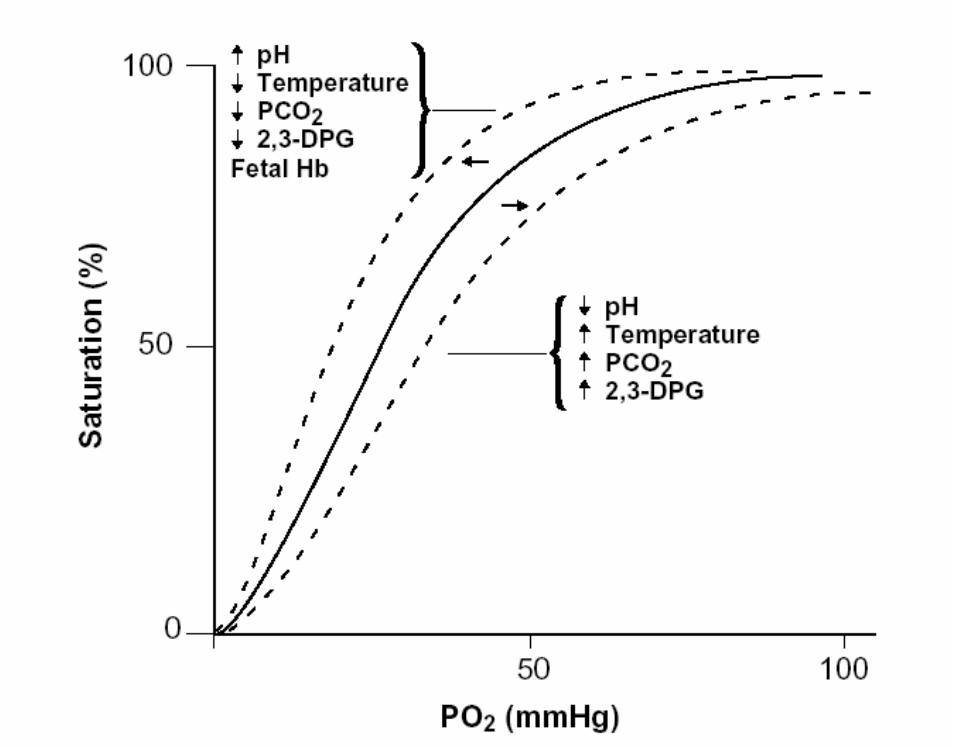


Figure 8-5 Oxyhemoglobin Dissociation Curve

8.3.2 Precautions

⚠WARNING

- **Pulse oximeter can overestimate the SpO_2 value in the presence of Hb-CO, Met-Hb or dye dilution chemicals.**
- **ES (Electrosurgery) equipment wire and SpO_2 cable must not be tangled up. Carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.**
- **Do not use this instrument and the sensors during magnetic resonance imaging (MRI). Induced current could potentially cause burns. The monitor may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.**
- **Do not put the SpO_2 sensor on extremities with arterial catheter or venous syringe.**
- **Do not use the supplied sterile SpO_2 sensors if the packaging or any sensor is damaged. Return them to the vendor.**
- **Do not perform SpO_2 monitoring and NIBP measurements on the same limb simultaneously. Obstruction of blood flow during NIBP measurements may adversely affect the reading of the SpO_2 value.**
- **Before performing the testing, check the sensor cable. After unplugging the SpO_2 sensor cable from the socket, the system shall display the error message "SPO2 SENSOR OFF" and give the audible alarm.**
- **Prolonged and continuous monitoring may increase the risk of burns at the site of the sensor. It is especially important to check the sensor placement, and ensure proper attachment on neonates and patients of poor perfusion or skin sensitive to light. Check the sensor location every 2–3 hours and move it to another location if the skin deteriorates. More frequent examinations may be required for different patients.**

NOTE

- **Place the SpO_2 sensor cable at the backside of the patient hand. Make sure the fingernail is just opposite to the light emitted from the sensor.**
- **The SpO_2 waveform is not proportional to the pulse volume.**

8.3.3 Monitoring Procedure

Follow the procedure as below:

1. Power on the monitor.
2. Attach the sensor to the proper site on the patient.
3. Plug the connector of the sensor extension cable into the SpO_2 connector on monitor.

The process of SpO_2 plethysmogram measurement is generally the same. But the SpO_2 sensor selection and placement depend on the patient type. When choosing a site for a sensor, refer to the directions for that sensor.

8.3.4 Measurement Limitations

If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by an alternate method, and then check the monitor and the sensor.

Inaccurate measurements may be caused by:

- incorrect sensor application or use.
- placement of a sensor on the same extremity with a blood pressure cuff, arterial catheter, or intravascular line.
- exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight (exposure to excessive illumination can be corrected by covering the sensor with a dark material).
- excessive patient motion.
- venous pulsations.
- intravascular dyes such as indocyanine green or methylene blue.
- Defibrillation.

Other physiological conditions or medical procedures that may interfere with the monitor's measurements include significant levels of dysfunctional hemoglobin, low perfusion, and dark pigment.

Loss of pulse signal can occur when

- the sensor is too tight.

- a blood pressure cuff is inflated on the same extremity as the one with an SpO_2 sensor attached.
- there is arterial occlusion proximal to the sensor.

Select an appropriate sensor, apply it as directed, and observe all warnings and cautions presented in the directions for use accompanying the sensor. Clean and remove any substances such as nail polish from the application site. Periodically check whether the sensor remains properly positioned on the patient.

If patient movement presents a problem, try one or more of the following remedies to correct the problem.

- Verify that the sensor is properly and securely applied.
- Move the sensor to a less active site.
- Use an adhesive sensor that tolerates some patient motion.
- Use a new sensor with fresh adhesive backing.

If poor perfusion affects the performance, consider using the Oxisensor R-15 sensor; it obtains measurements from the nasal septal anterior ethmoid artery, an artery supplied by the internal carotid. This sensor may obtain measurements when peripheral perfusion is relatively poor. For low peripheral perfusion, consider using the Nellcor RS-10 sensor, which is applied to the forehead or temple. These are sites that may be spared during peripheral vasoconstriction.

8.3.5 Nellcor Information

Nellcor Patents

This device is covered under one or more the following U.S. Patents: 4,802,486; 4,869,254; 4,928,692; 4,934,372; 4,960,126; 5,078,136; 5,485,847;5,743,263; 5,865,736; 6,035,223; 6,298,252; 6,463,310; 6,591,123; 6,675,031; 6,708,049; 6,801,791; Re.35,122 and international equivalents. U.S.A and international patents pending.

No Implied License

Possession or purchase of this device does not convey any express or implied license to use the device with replacement parts which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.

9 NIBP Monitoring

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9.1 Overview

The Non-invasive Blood Pressure (NIBP) module measures blood pressure using the oscillometric method. This monitor can be applied to adult, pediatric, and neonatal patients. Three modes of measurement are available: manual, automatic and continuous.

- Manual: Pressing starts an NIBP measurement.
- Auto: The NIBP measurement is performed automatically at a preset interval.
- Continuous: The NIBP measurement is performed as many times as possible in five minutes.

For settings of the monitoring modes, refer to ***4.6 INTERVAL***. The measured systolic pressure, mean pressure and diastolic pressure are displayed on the monitor. When the SpO_2 measurement is not been performed, the PR data can be obtained from the NIBP measurement.

⚠WARNING

- **Do not perform NIBP measurements on patients with sickle-cell disease or under any condition in which the skin is damaged or expected to be damaged.**
- **For a thrombasthemia patient, it is important to determine whether measurement of the blood pressure shall be done automatically.**
- **Ensure that the setting is correctly made when performing measurements on children. Incorrect patient type setting may cause a danger to the patient because adult blood pressure level is higher than children.**

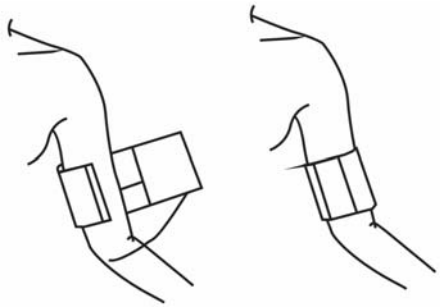
9.2 Monitoring Procedure

To perform NIBP measurement on a patient, follow the procedure below.

1. Power on the monitor.
2. Check the patient information area on the screen. If the patient type is incorrect, select a correct patient type in the PATIENT INFORMATION menu.
3. Plug the air hose in the NIBP cuff connector of the monitor.
4. Apply a cuff of proper size to the upper arm or the thigh of the patient.
5. Connect the cuff with the air hose.
6. Press to start the NIBP measurement.

9.2.1 Cuff Selection and Placement

1. Determine the patient limb circumference.
2. Select an appropriate cuff that is identified with the limb circumference.



NOTE

- **The width of the cuff should be either 40% of the limb circumference (50% for neonates) or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to circle 50-80% of the limb. The wrong size cuff can cause erroneous readings. If the cuff size is in question, use a larger cuff.**

3. Ensure that the cuff is completely deflated, place the cuff around the extremity being used and make sure the marking φ matches artery location.
4. Ensure that the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration or ischemia of the extremities.

5. Ensure that the cuff edge falls within the range of the <-> mark. If it does not, use a larger or smaller cuff that will fit better.
6. The limb chosen for taking the NIBP measurement should be placed at the same level as the patient's heart. If this is not possible, use the following method to correct the measurement result:

- If the cuff is placed higher than the heart level, add 0.75 mmHg (0.10 kPa) to the measured result for each centimeter of difference.
- If the cuff is placed lower than the heart level, deduct 0.75 mmHg (0.10 kPa) from the measured result for each centimeter of difference.

⚠WARNING

- **Do not apply the cuff to a limb that has an intravenous infusion or catheter in place. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.**
- **Make sure the air hose connecting the NIBP cuff and the monitor is not blocked, twisted, or tangled.**

9.2.2 Operation Guides

1. To start a manual NIBP measurement

- Enter the INTERVAL menu, set INTERVAL to MANUAL, and then press to start a manual NIBP measurement; or
- During the interval between two auto NIBP measurements, press to start a manual NIBP measurement.

2. To start an auto NIBP measurement

Enter the INTERVAL menu, set INTERVAL to a time (e.g. 5MIN), and then press to start an auto NIBP measurment. When this measurment finishes, the system will perform the NIBP measurment automatically as per the preset interval.

⚠WARNING

- **Auto non-invasive blood pressure measurements performed in long intervals may incur ischemia and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, change the position of the cuff on the patient or stop the blood pressure measurements immediately.**

3. To start a continuous NIBP measurement

Enter the INTERVAL menu, and then select CONTINUAL to start a continuous NIBP measurement. The monitor continues the NIBP measurement for five minutes.

4. To stop an NIBP measurement

During an auto, manual or continuous measurement, pressing stops the ongoing measurement.

NOTE

- **If you are in doubt about the accuracy of any reading(s), check the patient's vital signs with an alternative method before checking the function of the monitor.**

9.3 Measurement Limitations

The NIBP measurements are performed with the oscillometric method. The monitor detects the regular arterial pressure pulse. In some circumstances when the patient's condition makes it difficult to detect this pulse, the measurement becomes unreliable and the measurement time increases. You should be aware that the following conditions could interfere with the measurement, make the measurement unreliable, prolong the measurement, or even make a measurement impossible.

- Patient Movement

E.g. The patient is moving, shivering, or having convulsions.

- Arrhythmia

E.g. The patient's cardiac arrhythmia has caused an irregular heartbeat.

- Heart-lung Machine

E.g. Measurements will be impossible if the patient is connected to a heart-lung machine.

- Pressure Changes

E.g. The patient's blood pressure is changing rapidly over the period of time during which the arterial pressure pulses are being analyzed to obtain the measurement.

- Severe Shock

E.g. If the patient is in severe shock or hypothermia, reduced blood flow to the peripheries will cause reduced pulsation of the arteries.

- Heart Rate Extremes

The monitor is unable to perform pressure measurements at a heart rate of less than 40 bpm and greater than 240bpm.

9.4 Reset, Calibration and Test for Air Leakage

In the SYSTEM SETUP menu, select MAINTAIN. The menu appears, as follows.

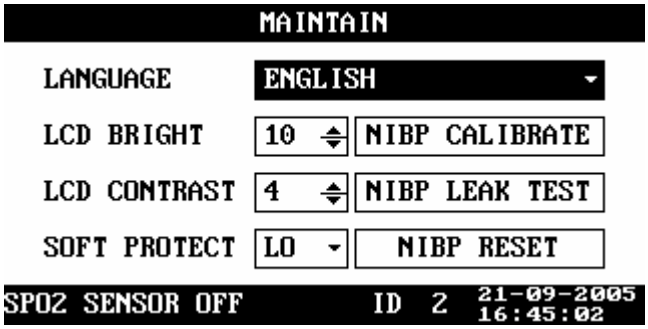


Figure 9-1

9.4.1 Reset

In the MAINTAIN menu, select NIBP RESET to restore the initial settings of the pressure pump. If the monitor fails to give a visual indication when the pressure pump is working improperly, by selecting this option, you can activate a self-test procedure, and restore the monitor to normal performance.

9.4.2 Calibration

If you select NIBP CALIBRATE in the MAINTAIN menu, the monitor starts the NIBP calibration and NIBP CALIBRATE changes to STOP CALIBRATE. Selecting STOP CALIBRATE, you can stop the calibration.

Calibrate the cuff pressure reading with a calibrated reference manometer (or mercury manometer) with accuracy higher than 1mmHg. To perform the calibration, follow the procedure shown below:

1. Remove the blood pressure cuff from the monitor and replace it with a rigid metal container or vessel with a capacity of 500±25ml.
2. Connect a calibrated reference manometer (with an error less than 0.8 mmHg), a ball pump using a T-piece, and the hoses together, and then connect them to the monitor, as shown in the following figure.
3. Select NIBP CALIBRATE.

4. Inflate the metal container with the ball pump until the reference manometer reads 0, then 50, and finally 200 mmHg.
5. The difference between the indicated pressure of the reference manometer and that of the monitor shall not exceed 3 mmHg. Otherwise, contact Mindray Customer Service.

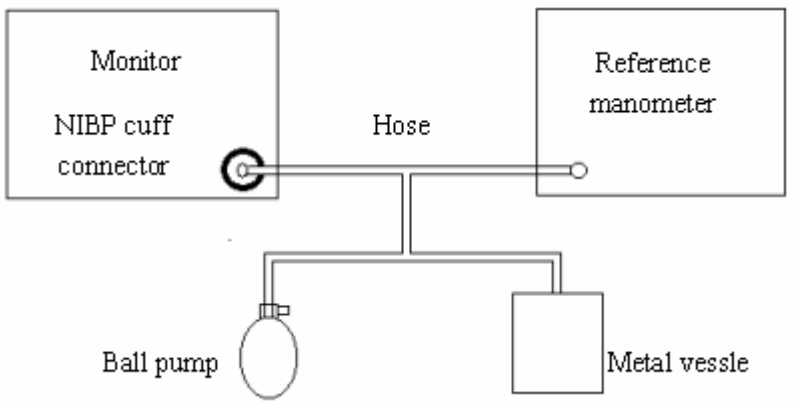


Figure 9-2 NIBP Calibration

NOTE

- **The calibration of the NIBP measurement should be performed every two years or performed according to the Hospital Procedure.**

9.4.3 Test for Air Leakage

In the MAINTAIN menu, selecting NIBP LEAK TEST, you can start testing the pump for air leakage. When the NIBP cuff is connected, selecting NIBP LEAK TEST, you can start the NIBP inflation and test whether the air leakage occurs in the airway. The test is passed if the system gives no indication in the test; the test is not passed if error information is displayed in the NIBP parameter area.

To test air leakage, follow the procedure below:

1. Connect the NIBP cuff to the NIBP cuff connector of the monitor.
2. Wrap the cuff around a cylinder of a proper size, as shown in the following figure.

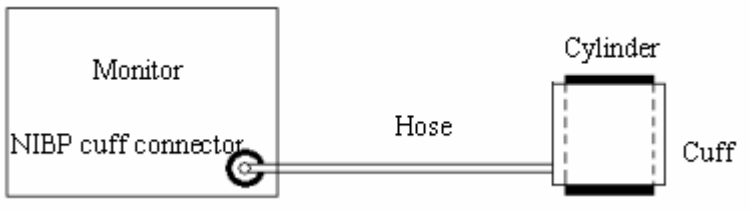


Figure 9-3 NIBP Leakage Test

3. Select NIBP LEAK TEST in the MAINTAIN menu. Then the system prompts “Pneum testing...”.
4. After approximately 20 seconds, the monitor will automatically open the deflation valve, ending the test.
5. If no message appears in the NIBP parameter area, it indicates the airway is in good condition and no air leak exists. However, if the system prompts “PNEUMATIC LEAK”, it indicates the airway may have an air leak. In this case, check for loose connections. After confirming that all connections are secure, perform the test again.

If there is still a failure, contact Mindray Customer Service.

NOTE

- **The pneumatic test, other than being specified in EN1060-1, is to be used to simply determine whether there are air leaks in the NIBP airway.**

9.5 Maintenance and Cleaning

⚠WARNING

- **Do not press the rubber hose on the cuff with excessive force**
- **When a reusable cuff is not connected to the monitor or is being cleaned, ALWAYS cover the rubber hose with a lid to avoid splashing liquid into the rubber hose or the monitor inadvertently.**

Reusable Blood Pressure Cuffs

The cuff is not suitable for dry-cleaned. Instead, it should be machine or hand washed. Hand washing, may prolong the service life of the cuff. Before washing, remove the latex rubber bladder. Allow the cuff to dry thoroughly after washing, and then reinsert the rubber bladder. The cuff can be disinfected by means of conventional autoclaving, gas, or radiation disinfection in hot air ovens, or sterilized by immersion in decontamination solutions. Remember to remove the rubber bladder if you use this method.

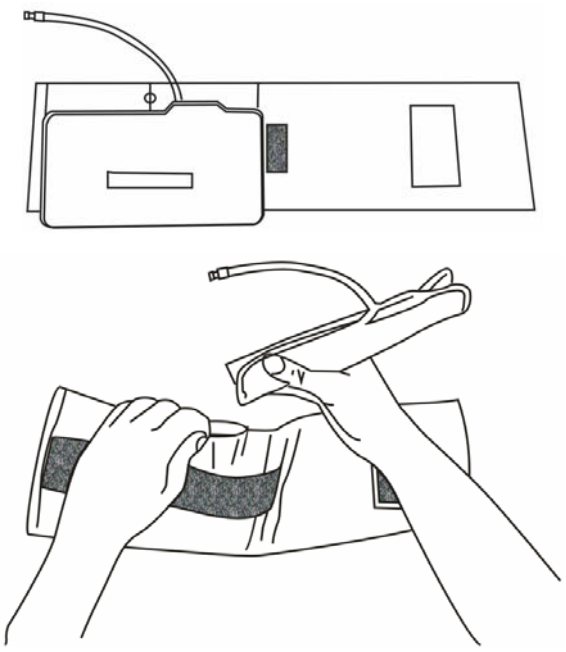


Figure 9-4 Replacing the rubber bladder

To replace the rubber bladder into the cuff:

1. Place the bladder on top of the cuff so the rubber hoses line up with the large opening on the long side of the cuff.
2. Roll the bladder lengthwise and insert it into the opening on the long side of the cuff, as shown in the above figure.
3. Hold the hoses and the cuff and shake the complete cuff till the bladder is in position.
4. Thread the rubber hoses from inside the cuff, and out through the small hole under the internal flap.

Disposable Blood Pressure Cuffs

Disposable cuffs are intended for a single patient use only. Do not sterilize or use autoclave sterilization for disposable cuffs.

NOTE

- **Disposable blood pressure cuffs must be recycled or disposed of properly.**

FOR YOUR NOTES

10 TEMP Monitoring

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10.1 Overview

The SmarTemp™ TEMP module is intended for monitoring oral, axillary and rectal temperature of adult and pediatric patients and axillary temperature of neonatoal patients. Be sure to set correct monitoring mode and position and to select appropriate temperature probe before taking measurement. TEMP TYPE can be set to PREDICT or MONITOR. The default TEMP TYPE is PREDICT.

- PREDICT MODE: In PREDICT mode, the TEMP probe warms up automatically as the probe is withdrawn from the probe sheath. Warminig up takes approximately 10s at 25℃ and when it is done, the monitor gives two beeps. Final temperature is obtained in approximately 20s and the monitor gives a beep. Temperature reading remains on the display till the probe is replaced into the its sheath. In the events that no accurate patient temperature is reached in this mode, or no measurement is taken in 60s after the probe is removed from the probe sheath, or the TEMP probe is not replaced in the its sheath, the monitor will automatically enter the MONITOR mode.
- MONITOR MODE: In MONITOR mode, final temperature is reached in 3 to 5 minutes and the temperature reading is continuously shown. In this mode, the monitor does not beep when the final temperature is obtained.

Please refer to ***4.1 Patient Information Setup*** for the setting of TEMP TYPE.

⚠Warning

- **The TEMP module shall only be operated under specified environment. When the probe is removed from the probe sheath, the monitor detects the ambient temperature. An auditory alarm will be triggered and the alarm message "ENV TEMP OVERRANGE" will display on the monitor if the ambient temperature is over range.**
- **For neonatal patient, only axillary temperature can be taken.**
- **Choose appropriate probe according to temperature position. Incorrect probe may result in erroneous measurement.**
- **Prolonged and continuous monitoring beyond 5 minutes is not recommended in any mode.**
- **In PREDICT mode, temperature probe shall be placed to the measured site as soon as probe warmup is complet, otherwise, inaccurate temperature reading may result.**
- **In MONITOR mode, the monitor stops measurement after performing measurement for five minutes later and the Temp reading disappears. Long-time Temp measurement may cause patient discomfort..**

10.2 Monitoring Procedure

10.2.1 TEMP position

The TEMP module is configured with 2 types of probe: oral/axillary probe (blue) and rectal probe (red). The blue oral/axillary probe shall only be used with blue probe sheath, while the red rectal probe shall only be used with red sheath. Be sure to select correct probe.

- Oral/axillary probe: This type of probe is intended for taking oral or axillary temperaure of adult and pediatric patients, or axillary temperature of neonatal patient.
- Rectal probe: This type of probe is intended for taking rectal temperature of adult and pediatric patient.

10.2.2 Oral Temperature Measurement

Please follow the procedures below to perform oral temperature measurement :

1. Make sure that the oral/axillary probe is connected to the probe connector and the indication lamp beside the temperature unit lights to indicate that TEMP module properly operates.
2. Set TEMP TYPE to PREDICT and TEMP POSITION to ORAL.
3. Unplug the probe from the probe sheath and insert it into a cover in the probe cover box. Press the probe handl down firmly until the cover engages with the probe.
4. After probe warmingup is ready, apply the probe under the patient's tongue from either side of the mouth. Verify that the probe reaches the rear sublingual pocket. Have the patient close his/her lips to hold the probe.
5. Hold the probe in place. Make sure that the probe contacts with the patient's oral tissue throughout the measurement.
6. The monitor will give a beep as the temperature measurement is complete. The temperature reading displays continuously.
7. Withdraw the probe from the patient's mouth when accurate temperature reading is obtained. Press firmly the ejection button on the top of the probe to eject the probe cover. Return the probe into the sheath.

"----" flashes on the temperature display area during TEMP measurement. Temperature reading displays when final temperature is reached.

10.2.3 Axillary Temperature Measurement

1. Make sure that the oral/axillary probe is connected to the probe connector and the indication lamp beside the temperature unit lights to indicate that TEMP module properly operates.
2. Set TEMP TYPE to PREDICT and TEMP POSITION to AXILLARY.
3. Unplug the probe from the probe sheath and insert it into a cover in the probe cover box. Press the probe handle down firmly until the cover engages with the probe.
4. After probe warmingup is ready, lift the patient's arm to show the entire armpit. Apply the probe as high as possible in the armpit. Check that the probe tip is completely surrounded by the axillary tissue. Lower the patient's arm so that it is tightly placed at the patient side. Keep the patient's arm and the probe in place throughout the measurement.
5. The monitor will give a beep as the temperature measurement is complete. The temperature reading is shown continuously.
6. Withdraw the probe from the patient's armpit when accurate temperature reading is obtained. Press firmly the ejection button on the top of the probe to eject the probe cover. Return the probe into the sheath.

"----" flashes on the temperature display area during TEMP measurement. Temperature reading displays when final temperature is reached.

10.2.4 Rectal Temperature Measurement

1. Make sure that the rectal probe is connected to the probe connector and the indication lamp beside the temperature unit lights to indicate that TEMP module properly operates.
2. Set TEMP TYPE to PREDICT and TEMP POSITION to RECTAL.
3. Unplug the probe from the probe sheath and insert it into a cover in the probe cover box. Press the probe handl down firmly until the cover engages with the probe.
4. After probe warmingup is ready, seperate the patient's buttocks with one hand and insert the probe 1.5cm inside the rectum with the other hand. For pediatric patient, depth of insertion shall be less . Tilt the probe so that it always contacts with patient's tissue. Lubricant can be used in rectal mode.

5. The monitor will give a beep as the temperature measurement is complete. The temperature reading is shown continuously.
6. Withdraw the probe from the patient's rectum when accurate temperature reading is obtained. Press firmly the ejection button on the top of the probe to eject the probe cover. Return the probe into the sheath.

"----" flashes on the temperature display area during TEMP measurement. Temperature reading displays when final temperature is reached.

10.2.5 Temperature Measurement in MONITOR Mode

Temperature measurement can be taken in MONITOR mode. The monitor automatically enters the MONITOR mode in the following two cases:

- Accurate temperature is not reached in the PREDICT mode.
- Neither measurement is taken nor the probe is replaced in the probe sheath in 60s after the probe is withdrawn from the sheath.

In MONITOR mode, temperature reading remains on the display as long as the probe is kept at the measurement position and the patient's temperature is within the measuring range. Final temperature value is reached in 3 to 5 minutes, however, the monitor does not beep in this mode.

Please follow the procedures below to perform temperature measurement.

1. Make sure that the probe is connected to the probe connector and the indication lamp beside the temperature unit lights to indicate that TEMP module properly operates.
2. Set TEMP TYPE to MONITOR and select appropriate TEMP POSITION.
3. Unplug the probe from the probe sheath and insert it into a cover in the probe cover box. Press the probe handl down firmly until the cover engages with the probe.
4. Take measurement according to above instructions as described in the PREDICT mode.
5. Remain the probe in place for 3 to 5 minutes till accurate measurement is reached.
6. Remove the probe when accurate temperature reading is obtained. Press firmly the ejection button on the top of the probe to eject the probe cover. Return the probe into the sheath.

10.3 Precautions

⚠Warning

- **Check the probe before taking temperature measurement. The prompt information "TEMP NO PROBE" will be presented and an auditory alarm will betriggered if the TEMP probe is disconnected from the probe connector.**
- **Check the disposable probe cover for damage before using. Never use any probe cover for temperature measurement in case of damage or contamination.**
- **Be careful to avoid damaging the TEMP probe. Replace the TEMP probe in the probe sheath if not in use.**
- **Calibration of the TEMP module is required every two years or according to your hospital's policy. Please contact our Customer Service if calibration is needed.**
- **Only TEMP probes and probe covers supplied by our company shall be used. The use of any other TEMP probe and probe cover may result in erroneous temperature measurements.**
- **Taking temperature without using probe cover or reusing the disposable probe cover may result in cross contamination.**

Note

- **TEMP TYPE automatically returns to the default PREDICT mode when the TEMP probe is replaced in the probe sheath.**
- **In the PREDICT mode, please cool the TEMP probe before taking measurement if ambient temperature is higher than 32.5℃.**
- **Patient actions may interfere with oral temperature readings. Ingesting hot or cold liquids, eating food, chewing gum or mints, brushing teeth, smoking, or performing strenuous activities may affect temperature readings for up to 20 minutes after the activity has ended.**
- **Prolonged and continuous monitoring for more than 3 minutes in oral or rectum mode or 5 minute in axillary mode is not recommended.**
- **In the axillary mode, the probe shall directly contact with patient's skin. Measuring through patient's clothes or long-term exposal of patient's armpit to the air may result in inaccurate temperature reading.**
- **In the rectal mode, incorrect probe placement may result in bowel perforation. Washing hands after temperature measurement is complete will significantly reduce the risk of cross infection and nosocomial contamination.**

10.4 Maintenance and Cleaning

⚠Warning

- **Before cleaning the probe and probe sheath make sure that the monitor is turned off and disconnected from AC power.**
- **Never immerse or soak the probe.**
- **Clean/Disinfect the probe and probe sheath Regularly.**
- **Do not reuse the disposable probe cover.**

The TEMP probe and the probe sheath configured for the monitor is reusable. Please follow the procedures below to perform cleaning/disinfection.

1. Disconnect the probe with the probe connector and remove the probe sheath from the monitor.
2. Wipe the inner and outer surface of the probe sheath with a soft cloth moistened with cleaning agent. Soak the probe sheath in mild detergent solution as necessary for cleaning.

We recommend to use the following solution for clearing/disinfection: ethanol 70%, isopropanol 70%, glutaraldehyde-type(2%) liquid disinfectants, 10% chlorine bleach solution.

⚠Warning

- **Do not use hard or sharp objects to clear the probe sheath. This may damage the sheath and result in TEMP module malfunction.**
- **Do not disinfect the probe sheath by steam, heat or gas.**
- **Do not autoclave the probe sheath.**

- Allow all the parts dry thoroughly before reinstalling the probe.
- Reconnect the probe to the monitor. Check that the probe clicks in place.
- Return the probe sheath to the monitor. Check that the sheath clicks in place.
- Place the TEMP probe into the probe sheath.

11 Accessories

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⚠WARNING

- **Use the specified accessories for this monitor. Accessories of other types may cause damage to this monitor.**

11.1 SpO_2 Accessories

11.1.1 Mindray SpO_2 Accessories

Accessory	**PN**
6Pin SpO_2 Cable	0010-20-42594
Finger SpO_2 Sensor (Resuable, Mindray 512B)	512B-30-90134
Finger SpO_2 Sensor (Resuable, Mindray 512D)	512D-30-90200
Finger SpO_2 Sensor (Reusable, Mindray 512E)	512E-30-90390
Adult Finger SpO_2 Sensor (Reusable, Mindray 512F)	512F-30-28263
Pediatric Finger SpO_2 Sensor (Reusable, Mindray 512G)	512G-30-90607
Pediatric Finger SpO_2 Sensor (Reusable, Mindray 512H)	512H-30-79061
Multisite SpO_2 Sensor (Reusable, Mindray 512B)	518B-30-72107
Adult Single-patient SpO_2 Sensor (Disposable, Mindray 520A)	520A-30-64101
Pediatric Single-patient SpO_2 Sensor (Disposable, Mindray 520P)	520P-30-64201
Infant Single-patient SpO_2 Sensor (Disposable, Mindray 520I)	520I-30-64301
Neonate Single-patient SpO_2 Sensor (Disposable, Mindray 520N)	520N-30-64401
Small SpO_2 Ear Sensor (ES-3212-9, Envitec)	0010-10-12392
Adult Oxygen Sensor (Disposable, MAX-A (>30Kg))	0010-10-12202
Pediatric Oxygen Sensor (Disposable, MAX-P (10-50Kg))	0010-10-12203
Infant Oxygen Sensor (Disposable, MAX-I (3-20Kg))	0010-10-12204
Neonatal/Adult Oxygen Sensor (Disposable, MAX-N (<3Kg or >40Kg))	0010-10-12205
Adult SpO_2 Sensor (Reusable, DS-100A, Nellcor KIT)	7000-10-24520
Adult Oxygen Sensor (Reusable, DS-100A)	9000-10-05161
OXI-P/I Pediatric/Infant Sensor and Sensor Wraps	9000-10-07308
OXI-A/N Adult/Neonatal Sensor and Sensor Wraps	9000-10-07336
Disposable SpO_2 Sensor for Adults (2211-1, Envitec)	0010-10-12333
Disposable SpO_2 Sensor for Pediatrics (2211-2, Envitec)	0010-10-12334
Disposable SpO_2 Sensor for Infants (2211-5, Envitec)	0010-10-12335
Disposable SpO_2 Sensor for Neonates (2211-6, Envitec)	0010-10-12336

11.1.2 Masimo SpO_2 Accessories

Accessory	**PN**
6Pin SpO_2 Cable (MASIMO LNCS)	0010-30-42625
Disposable SpO_2 Sensor for Pediatrics/Neonates (LNCS-NeoPt-L)	0010-10-42626
Disposable SpO_2 Sensor for Neonates (LNCS-Neo-L)	0010-10-42627
Disposable SpO_2 Sensor for Infants (LNCS-Inf-L)	0010-10-42628
Disposable SpO_2 Sensor for Pediatrics (LNCS-Pdt)	0010-10-42629
Disposable SpO_2 Sensor for Adults (LNCS-Adt)	0010-10-42630
Reusable SpO_2 Sensor for Adults (LNCS DC-I)	0010-10-42600
Reusable SpO_2 Sensor for Pediatrics (LNCS-DCIP)	0010-10-42634
Reusable SpO_2 Multisite Sensor (LNCS-YI)	0010-10-43016

11.1.3 Nellcor SpO_2 Accessories

Accessory	**PN**
6Pin SpO_2 Cable (NELLCOR)	0010-20-42595
Adult Oxygen Sensor (Disposable, MAX-A (>30Kg))	0010-10-12202
Pediatric Oxygen Sensor (Disposable, MAX-P (10-50Kg))	0010-10-12203
Infant Oxygen Sensor (Disposable, MAX-I (3-20Kg))	0010-10-12204
Neonatal/Adult Oxygen Sensor (Disposable, MAX-N (<3Kg or >40Kg))	0010-10-12205
Adult SpO_2 Sensor (Reusable, DS-100A,Nellcor KIT)	7000-10-24520
Adult Oxygen Sensor (Reusable, DS-100A)	9000-10-05161
OXI-P/I Pediatric/Infant Sensor and Sensor Wraps	9000-10-07308
OXI-A/N Adult/Neonatal Sensor and Sensor Wraps	9000-10-07336

11.2 NIBP Accessories

Accessory	PN
NIBP Hose (CE)	509B-30-06259
Neonatal NIBP Hose (CE)	509B-30-06260
Infant 10 to 19 cm Arm Circumference (CM1201)	0010-30-12157
Child 18 to 26 cm Arm Circumference (CM1202)	0010-30-12158
Adult 25 to 35 cm Arm Circumference (CM1203)	0010-30-12159
Large Adult 33 to 47 cm Arm Circumference (CM1204)	0010-30-12160
Adult Thigh 46 to 66 cm Arm Circumference (CM1205)	0010-30-12161
M1872A Disposable Cuff (Philips/Size #4/7.1-13.1cm)	900E-10-04873
M1870A Disposable Cuff (Philips/Size #3/5.8-10.9cm)	900E-10-04874
M1868A Disposable Cuff (Philips/Size #2/4.3-8.0cm)	900E-10-04875
M1868A Disposable Cuff (Philips/Size #1/3.1-5.7cm)	900E-10-04876
Single-Patient Neonate Blood Cuff	001B-30-70677
Single-Patient Neonate Blood Cuff	001B-30-70678
Single-Patient Neonate Blood Cuff	001B-30-70679
Single-Patient Neonate Blood Cuff	001B-30-70680
Single-Patient Infant Blood Cuff	001B-30-70682
Single-Patient Child Blood Cuff	001B-30-70683
Single-Patient Adult Blood Cuff	001B-30-70684
Single-Patient Large Adult Blood Cuff	001B-30-70685
Single-Patient Adult Thigh Blood Cuff	001B-30-70686

11.3 TEMP Accessories

Predictive temperature probe (oral/axillary)	6006-30-39598
Predictive temperature probe (rectal)	6006-30-39599
Red probe sheath	M09A-20-62062-51
Blue probe sheath	M09A-20-62062
Disposable probe cover (20 pcs)	M09A-20-62124
Disposable probe cover (200 pcs)	M09A-30-62126
Disposable probe cover (2000 pcs)	M09A-30-62128

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Appendix A Product Specifications

A.1 Safety Classifications

Classification of the State Food and Drug Administration of China	Ⅱ
Type of protection against electrical shock	Class I; internally/externally powered equipment Where the integrity of the external protective earth (ground) in the installation or its conductors is in doubt, the equipment shall be operated from its internal electric power supply (batteries).
Degree of protection against electric shock	SpO_2/NIBP/TEMP: CF
Degree of protection against hazards of ignition of flammable anesthetic mixtures	Not suitable (ordinary)
Degree of protection against harmful ingress of water	Not suitable (ordinary)
Mode of operation	Continuous
Equipment type	Portable

A.2 Environmental Specifications

Operating ambient temperature	0 to 40 ºC 10 to 40 ºC (50 to104 ºF) (SmarTemp™ TEMP module)
Operating relative humidity	15 to 95%, non-condensing
atmospheric pressure at working conditon (operating altitude)	70 to 106KPa -500 to 4600m, -1640 to 15092ft
Storage temperature	-20 to 60 ºC
Storage relative humidity	10 to 95%, non-condensing
atmospheric pressure in Storage (Storage altitude)	22 to 107.4KPa -500 to 13100m, -1640 to 42979ft

A.3 Power Requirements

AC mains	
Voltage	100 to 240V
Frequency	50/60Hz
Power	70VA
Battery	
Number of batteries	1
Battery type	Sealed lead-acid battery or lithium-ion battery
Time to shutdown	5 to 15min (after the first battery-low alarm)
Sealed lead-acid battery	
Nominal voltage	12VDC
Battery capacity	2.3Ah
Typical operating time	260min The monitor runs on power supplied by the new fully-charged battery in the following conditions: Ambient temperature: 25°C Monitor configuration: SpO_2 (continuous measurement) and NIBP (one auto NIBP measurement per 15 minute)
Charge time	A maximum of 8h
Lithium-ion battery	
Nominal voltage	11.1VDC
Battery capacity	4.4Ah
Typical operating time	620min The monitor runs on power supplied by the new fully-charged battery in the following conditions: Ambient temperature: 25°C Monitor configuration: SpO_2 (continuous measurement) and NIBP (one auto NIBP measurement per 15 minute)
Charge time	A maximum of 8h

A.4 Hardware Specification

Size	177 × 240 × 170mm (width × height × depth))
Weight	< 3.5kg (battery included)
LCD	
Type	Monochrome FSTN
Size	80.3 × 41.0mm
Resolution	320 × 160 pixels
7-segment LED Digit Displays	
Groups	5
Function	Refer to ***2.2.1 Front Panel***
LED indicator	
Number	6
Function	Refer to ***2.2.1 Front Panel***
Recorder	
Type	Thermal dot array
Horizontal resolution	160dots/cm (paper speed: 25mm/s)
Vertical resolution	80dots/cm
Paper width	50mm
Paper length	30m
Paper speed	25 mm/s
Number of waveform channels	1
Connectors	
Power supply	1 AC power connector
Nurse call	1
Network	1 standard RJ45 network connector, 100 BASE-TX
Serial port	1 standard RS-232 serial port

A.5 Signal Output

Standards	Meet the requirements of EC60601-1 for short-circuit protection and leakage current
Nurse call output	
Driving mode	Driven by relay
Electrical specification	≤ 60W, ≤ 2A, ≤36 VDC, ≤ 25VAC
Isolation voltage	> 1500VAC
Working mode	N/O or N/C (optional)

A.6 SpO_2 Specification

A.6.1 Mindray SpO_2 Specification

Parameter	**Specification**
SpO_2	
Measurement range	0 to 100%
Resolution	1%
Accuracy	70 to 100%: ±2% (adult/pediatric, in non-motion conditions) 70 to 100%: ±3% (neonate, in non-motion conditions) 0 to 69%: Undefined
Update period	1s
PR	
Measurement range	20 to 254bpm
Resolution	1bpm
Accuracy	±3 bpm (in non-motion conditions)
Update period	1s

A.6.2 Masimo SpO_2 Specification

Parameter	**Specification**
SpO_2	
Measurement range	1 to 100%
Resolution	1%
Accuracy	70 to 100%: ±2% (adult/pediatric, in non-motion conditions) 70 to 100%: ±3% (neonate, in non-motion conditions) 70 to 100%: ±3% (in motion conditions) 0 to 69%: Undefined
Update period	1s

PR	
Measurement range	25 to 240bpm
Resolution	1bpm
Accuracy	±3 bpm (in non-motion conditions) ±5 bpm (in motion conditions)
Update period	1s

A.6.3 Nellcor SpO_2 Specification

Parameter	**Specification**		
SpO_2 measurement range and accuracy	Sensor	Range	Accuracy*
	MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I, MAX-FAST	70 to 100% 0% to 69%	±2% Undefined
	OxiCliq A, OxiCliq N, OxiCliq P, OxiCliq I	70 to 100% 0% to 69%	±2.5% Undefined
	D-YS, DS-100A, OXI-A/N, OXI-P/I	70 to 100% 0% to 69%	±3% Undefined
	MAX-R, D-YSE, D-YSPD	70 to 100% 0% to 69%	±3.5% Undefined
PR measurement range and accuracy	20 to 250 bpm: ±3 bpm 251 to 300 bpm: Undefined		
Update period	1s		
*: When sensors are used on neonatal subjects as recommended, the specified accuracy range is increased by ±1 digit, to account for the theoretical effect on oximeter measurements of fetal hemoglobin in neonatal blood.			

A.7 NIBP Specification

Parameter	**Specification**			
NIBP				
Method	Oscillation			
Displayed parameters	Systolic pressure, diastolic pressure and mean pressure, Pulse rate			
Mode of operation	Manual, auto and continuous			
Measurement range in normal mode	mmHg	Adult	Pediatric	Neonate
	Systolic pressure	40 to 270	40 to 200	40 to 135
	Diastolic pressure	10 to 210	10 to 150	10 to 100
	Mean pressure	20 to 230	20 to 165	20 to 110
Accuracy	Maximum average error: ±5mmHg Maximum standard deviation: 8mmHg			
Resolution	1mmHg			
Over-pressure protection	Adult: 297±3 mmHg Pediatric: 240±3 mmHg Neonate: 147±3 mmHg			
Measurement range in high pressure mode	Only applicable to adult patients Systolic pressure: 40 to 330mmHg Diastolic pressure: 10 to 270mmHg Mean pressure: 20 to 290mmHg			
PR				
Measurement range	40 to 240bpm			
Resolution	1bpm			
Accuracy	±2bpm or 2%, whichever is larger			

A.8 TEMP Specification

Parameter	**Specification**
Displayed parameter	TEMP
Measurement range	25 to 44 ºC（77 to 111.2 ºF）
Resolution	In MONITOR mode: 0.1ºC (0.2 ºF)
Accuracy	In MONITOR mode: 25 to 32 ºC (77 to 89.6 ºF): ±0.2 ºC (± 0.3 ºF) including 32 ºC（89.6 ºF） In MONITOR mode: 32 to 44 ºC (89.6 to 111.2 ºF): ±0.1ºC （±0.2 ºF）excluding 32 ºC（89.6 ºF）
Typical prediction time	< 16 s (Count from the time moment when temperature "----" starts flashing)

Appendix B EMC

The equipment meets the requirements of IEC 60601-1-2:2001+A1:2004.

NOTE

- **Use of accessories, transducers, and cables other than those specified may result in increased emission**
- **n and/or decreased immunity of the equipment.**
- **The equipment should not be used adjacent to or stacked with other equipment, and if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.**
- **The equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.**
- **The equipment may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.**
- **Operation of the device, in the case that the patient physiological signal is lower than the minimum amplitude and/or value specified in the product specifications, may cause inaccurate results.**
- **Portable and mobile RF communications equipment can affect this equipment.**

TABLE 1

Guidance and MINDRAY declaration — electromagnetic emissions		
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment — guidance**
RF emissions CISPR 11	Group1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The equipment is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Compliance	

TABLE 2

Guidance and MINDRAY declaration — electromagnetic immunity			
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment — guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines (>3m).	±2 kV for power supply lines ±1 kV for input/output lines (>3m)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV different mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, Short interruptions and voltage variation on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in UT) for 0.5 cycle 40% U_T (60% dip in UT) for 5 cycle 70% U_T (30% dip in UT) for 25 cycle <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in UT) for 0.5 cycle 40% U_T (60% dip in UT) for 5 cycle 70% U_T (30% dip in UT) for 25 cycle <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of our product requires continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

U_T is the A.C. mains voltage prior to application of the test level.

TABLE 3

<table>
<tr><td colspan="4">Guidance and MINDRAY declaration — electromagnetic immunity</td></tr>
<tr><td colspan="4">The equipment is intended for use in the electromagnetic environment specified below.
The customer or the user of the equipment should assure that it is used in such an environment</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 Test level</td><td>Compliance level</td><td>Electromagnetic environment — guidance</td></tr>
<tr><td>Conduced RF IEC 61000-4-6</td><td>3 Vrms
150kHz to 80MHz</td><td>3 Vrms</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = 1.2 \times \sqrt{P}$
$d = 1.2 \times \sqrt{P}$ 80 MHz to 800 MHz
$d = 2.3 \times \sqrt{P}$ 800 MHz to 2.5GHz
where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range b Interference may occur in the vicinity of equipment marked with the following symbol: </td></tr>
<tr><td>Radiated RF IEC 61000-4-3</td><td>3 V/m
80MHz to 2.5GHz</td><td>3V/m</td></tr>
<tr><td colspan="4">Note — At 80 MHz and 800 MHz, the higher frequency range applies.
Note — These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered.</td></tr>
</table>

If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

b Over the frequency ranges 150kHz to 80MHz, field strengths should be less than 3V/m.

TABLE 4

Recommended separation distances between portable and mobile RF communication and the equipment

The equipment is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the equipment as recommended below, according to the maximum output power of the communication equipment.

Rated Maximum Output power of Transmitter W (Watts)	**Separation Distance According to Frequency of Transmitter M (Meters)**		
	150kHz -80MHz $d = 1.2\sqrt{P}$	80MHz -800MHz $d = 1.2\sqrt{P}$	800MHz -2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.38
100	11.67	11.67	23.34

For transmitters at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note — At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note — These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix C Alarm Messages and Prompt Information

C.1 Physiological Alarm Messages

Note: XX represents the parameters being monitored, such as PR, SpO_2, NIBP, etc. The "L" field indicates the alarm level, and 1 means high, 2 means medium, 3 mean low.

Alarm message	L	Cause	Measure
XX TOO HIGH	2	XX value exceeds the upper alarm limit.	Make sure the alarm limits are appropriate for the patient, and check the patient's condition.
XX TOO LOW	2	XX value is lower than the lower alarm limit.	
NO PULSE	1	The pulse signal of the patient is so weak that the monitor cannot perform pulse analysis.	Check the connection of the sensor and the patient's condition.

C.2 Technical Alarm Messages

Note: XX represents the parameter module like NIBP or SpO_2, or the parameters being monitored like PR and SpO_2; the A field indicates whether an alarm can be completely cleared; the B field indicates whether the visual and audible indications of an alarm can be cleared; the L field refers to the alarm level; * implies the level is user-adjustable.

C.2.1 General Alarm Messages of Parameter Modules

Alarm message	A	B	L	Cause	Measure
XX INIT ERR N	Yes	No	1	XX module initialization error N	Restart the monitor. If the error remains, contact Mindray for
Note: N stands for the error number.					

XX COMM STOP	No	No	1	Failure in communication between XX module and the main board	repair.
XX COMM ERROR	Yes	No	1	Error in communication between XX module and the main board	
XX ALM LMT ERR	No	No	1	The alarm limit of the XX parameter is changed inadvertently.	If the error remains, contact Mindray for repair.
XX EXCEED	No	No	1	The measured XX parameter value exceeds the measurement range.	

C.2.2 NIBP Module Alarm Messages

Alarm message	**A**	**B**	**L**	**Cause**	**Measure**
NIBP SELFTEST ERR	Yes	Yes	1	Error in NIBP initialization.	Select RESET in the INTERVAL menu. If the error remains, contact Mindray for repair.
LOOSE CUFF	No	Yes	2	The NIBP cuff is not properly connected.	Check the patient's condition, and check if the patient type is correct. Replace with a proper cuff and connect it correctly. If the problem still exists, contact Mindray for repair.
AIR LEAK	No	Yes	2	Leak in the airway	
CUFF TYPE ERR	No	Yes	2		
PNEUMATIC LEAK	No	Yes	2		
AIR PRESSURE ERROR	No	Yes	2	Failures occur in the pulse measurement. The monitor cannot perform measurement, analysis, or calculation.	
WEAK SIGNAL	No	Yes	2		
SIGNAL SATUATED	No	Yes	2		
NIBP Over Range	No	Yes	2		Check the patient's condition, and check if the patient type is correct. Replace with a proper cuff and connect it correctly. If the
EXCESSIVE MOTION	No	Yes	2	Excessive motion of the patient's arms	
OVER PRESSURE	No	Yes	2	The airway might be blocked.	

Alarm message	A	B	L	Cause	Measure
NIBP SYSTEM FAILURE	No	Yes	2	Failure occurs in the pulse measurement. The monitor cannot perform measurement, analysis, or calculation.	problem still exists, contact Mindray for repair.
NIBP TIME OUT	No	Yes	2		
MEASURE FAIL	No	Yes	2		
NIBP RESET ERROR	No	Yes	2	Illegal reset comes out during the NIBP measurement.	Check if the airway is blocked. Deal with the blocking and perform the measurement again. If the problem still exists, contact Mindray for repair.

C.2.3 Mindray SpO_2 Module Alarm Messages

Alarm message	A	B	L	Cause	Measure
SPO2 SENSOR OFF	No	Yes	2	The sensor is disconnected from the patient or the monitor.	Make sure that the sensor is placed on the patient's finger or other parts and the monitor is connected to cables correctly.
SPO2 LOW PERFUSION	No	No	2	The pulse signal is too weak.	Move the sensor to a site with better perfusion.

C.2.4 Masimo SpO_2 Module Alarm Messages

Alarm message	A	B	L	Cause	Measure
SPO2 SENSOR OFF	Yes	Yes	2	The sensor is disconnected from the patient or the monitor.	Make sure that the sensor is placed on the patient's finger or other parts and the monitor is connected to cables correctly.

Alarm message	A	B	L	Cause	Measure
SPO2 PULSE SEARCH	No	No	2	The monitor is searching for the pulse signal of the patient.	If the pulse reading is not displayed after 30 seconds, check if the sensor is properly connected to the patient. Change the sensor site for better signals if necessary.
SPO2 INTERFERENCE	No	No	2	The pulse signals are subject to great external interference.	Reduce or remove external interference.
SPO2 LOW PERFUSION	No	No	2	The pulse signal detected by the monitor is too weak.	Change the sensor site for better signals.
SPO2 TOO MUCH LIGHT	No	No	2	Too much light on the patient and sensor.	Turn down or off the lighting, move the sensor to a place of weaker light or cover the sensor.
UNKNOWN SPO2 SENSOR	No	No	2	The monitor cannot recognize the SpO_2 sensor type.	Check whether the type of the sensor is correct.
SPO2 BOARD FAULT	No	No	1	The SpO_2 board malfunctions and might be unable to measure the pulse signals correctly.	Stop using the SpO_2 module, and contact biomedical engineers or Mindray for maintenance.
SPO2 SENSOR FAULT	No	No	1	The sensor is damaged.	Stop using the sensor.
SPO2 NO SENSOR	Yes	Yes	3	The sensor is disconnected from the patient or the monitor, or the sensor is not properly connected.	Disconnect and reconnect the sensor as directed by the instructions. If the alarm remains, the sensor or the cable might have been damaged.

Alarm message	A	B	L	Cause	Measure
				The SpO_2 sensor is inserted upside down.	Disconnect and reconnect the sensor as directed by the instructions. Pay attention to the mark on the sensor.
SPO2 WEAK SIGNAL	No	No	3	The pulse signals detected by the monitor are of poor quality.	Move the sensor to a site with better signals.
WRONG SPO2 SENSOR	No	No	3	The SpO_2 sensor is incompatible to the monitor, or is damaged.	Stop using the sensor.

C.2.5 Nellcor SpO_2 Module Alarm Messages

Alarm message	A	B	L	Cause	Measure
SPO2 SENSOR OFF	No	Yes	2	The sensor is disconnected from the patient or the monitor.	Make sure that the sensor is placed on the patient's finger or other parts and the monitor is connected to cables correctly.
SPO2 NO SENSOR	Yes	Yes	2	The sensor is disconnected from the patient or the monitor, or the sensor is not connected properly.	Disconnect and reconnect the sensor as directed by the instructions. If the alarm remains, the sensor or the cable might have been damaged.
				The SpO_2 sensor is inserted upside down.	Disconnect and reconnect the sensor as directed by the instructions. Pay attention to the mark on the sensor.
SPO2 INTERFERENCE	No	No	2	The pulse signals are subject to great external interference.	Reduce or remove external interference.
SPO2 BOARD FAULT	No	No	1	The SpO_2 board malfunctions and might be unable to measure the pulse signals correctly.	Stop using the SpO_2 module, and contact biomedical engineers or Mindray for maintenance.
SPO2 MOTION	No	No	2	The patient is moving.	Reduce patient motion.
SPO2 SENSOR FAULT	No	No	1	The sensor is damaged.	Stop using the sensor.
SPO2 WEAK SIGNAL	No	No	2	The SpO_2 signal is weak.	Change the sensor site for better signals.
SPO2 WEAK PULSE	No	No	2	The detected pulse signal is too weak.	

C.2.6 SmarTemp™ TEMP Module Alarm Messages

Alarm message	A	B	L	Cause	Action
WARMUP TIMED OUT	Yes	Yes	2	TEMP probe initial temperature is too high.	Cool the TEMP probe before taking measurement.
WARMING RESISTOR ERR	No	No	2	The warming resistor in the TEMP probe fails.	Replace the TEMP probe.
TEMP PROBE MISPLACED	Yes	No	2	TEMP probe is not placed in the sheath or the probe sheath is not in place.	1. Check that the probe sheath is in place. 2. Replace the TEMP probe in the sheath properly.
ENV TEMP OVERRANGE	No	Yes	2	The ambient temperature is beyond the measuring range.	Take measurement in proper working condition.
TEMP VOLTAGE ERR	No	Yes	2	Supply voltage is too high or too low.	Check the power supply.
TEMP NO PROBE	No	Yes	2	The TEMP probe is disconnected from the TEMP module.	Reconnect the probe with the TEMP module.
TEMP PREDICTION ERR	Yes	Yes	3	Improper temperature measurement	Take TEMP measurement again correctly.
TEMP SELFTEST ERR	No	No	1	An error occurs during the TEMP module initialization	Replace the TEMP module
TEMP PROBE OFF	No	Yes	3	TEMP probe does not contact with the patient.	Take measurement again after the probe warms up.
TEMP OVER HIGH LIMIT	No	No	1	The temperature measured is too high or measurement error	Lower the measured temperature or replace the TEMP module.
TEMP OVER LOW LIMIT	No	No	1	The temperature measured is too low or measurement error	Raise the measured temperature or replace the TEMP module.

TEMP WRONG PROBE	No	No	1	A TEMP probe not supplied by our company is used.	Replace with a TEMP probe we supply.
TEMP COMM ERR	No	No	1	TEMP module is not available or TEMP module fails	Check if a TEMP module is available. If yes, replace the TEMP module.

C.2.7 Recorder Module Alarm Messages

Alarm message	**A**	**B**	**L**	**Cause**	**Measure**
RECORDER INIT ERR N	Yes	No	2	An error occurs during the recorder initialization.	Contact the hospital's engineers or Customer Service of Mindray.
Note: N represents the error number.					
REC SELFTEST ERR	Yes	No	2	An error might occur to the RAM, ROM and CPU watchdog.	Restart the recorder. If the error remains, contact Mindray for repair.
RECORDER VLT HIGH	No	No	1	A problem occurs to the system power.	If this alarm message is given for many times, contact Mindray for repair.
RECORDER VLT LOW	No	No	1		
RECORDER HEAD HOT	No	No	1	The thermal head of the recorder is too hot.	Resume the recording after the recorder cools down completely. If the problem still exists, contact Mindray for repair.
REC HEAD WRONG POS.	Yes	Yes	2	The thermal head of the recorder is in wrong position.	Restore the control lever of the recorder to its previous position.
REC OUT OF PAPER	Yes	Yes	2	The recorder paper is used up.	Replace with a new paper roll.
RECORDER PAPER JAM	No	No	2	The recorder has recorded data on paper for 30m's long or more.	Place the recorder correctly and try again.

RECORDER COMM ERR	Yes	No	2	Error in recorder communication.	Open the RECORD menu and select the CLEAR REC TASK option. If the problem remains, contact Mindray for repair.
TOO MANY REC TASKS	No	No	2	Quite a few alarm events occur at the same time.	Check the patient's condition and the alarms. Open the RECORD menu and select the CLEAR REC TASK option. If the problem remains, contact Mindray for repair.
RECORDER PAPER W.P.	Yes	Yes	2	The paper roll of the recorder is not placed in the correct position.	Place the paper roll correctly.
REC S. COMM ERR	Yes	No	2	Error in recorder communication.	Open the RECORD menu and select the CLEAR REC TASK option. If the problem remains, contact Mindray for repair.
REC NOT AVAILABLE	No	No	2	Error in the recorder work mode.	

C.2.8 System Alarm Messages

Alarm message	**A**	**B**	**L**	**Cause**	**Measure**
REAL CLOCK NEED SET	No	No	1	The system time is incorrect.	Reset the system time and then restart the monitor.
REAL CLK NOT EXIST	No	No	1	There is no button battery, or the battery power is depleted.	Add, or replace with a new button battery.
KEYBOARD INIT ERR N	No	No	1	Keyboard error. The keyboard cannot be used.	Contact Mindray for repair.
Note: N represents the error number.					
KEYBOARD ERROR	No	No	2		
NET INIT ERR (G.)	No	No	2	The system cannot be connected to the	
NET INIT ERR (Reg)	No	No	2		

NET ERR (Run 1)	No	No	2	network due to problems in the monitor's network part.	
NET ERR (Run 2)	No	No	2		
12V TOO HIGH	No	No	1	A problem occurs to the system power.	If this alarm message is given for many times, contact Mindray for repair.
12V TOO LOW	No	No	1		
BATTERY TOO LOW	No	No	1	The battery voltage is too low.	Connect the monitor to AC mains to charge the battery.
DATAOUT FAIL	Yes	Yes	2	A failure occurs in data transmission during the data output.	Re-output the data.
NET ERROR	Yes	Yes	2	An error occurs in the network connection during the data output.	Check the network connection.

C.3 Prompt Messages

Prompt message	**Cause**	**Measure**
SEARCH PULSE	The SpO_2 module is searching the pulse.	Wait till the end of the search.
Recorder		
REC INITIALIZING	The recorder is being initialized.	Wait till the end of the initialization.
RECORDER BUSY	The recorder is recording data.	Wait till the end of the recording.
NIBP module		
Manual measure...	The NIBP module is performing a manual measurement.	Wait till the end of the measurement.
Cont measuring...	The NIBP module is performing a continuous measurement.	
Auto measuring...	The NIBP module is performing an automatic measurement.	
Resetting...	The NIBP module is being reset.	Wait till the end of the reset.

Prompt message	**Cause**	**Measure**
Please start	The interval for automatic measurement has been selected.	Press NIBP to start the measurement.
Calibrating...	The NIBP module is being calibrated.	Wait till the end of the calibration.
Calibration over	The calibration is finished.	None
Testing leak...	The NIBP module is testing for air leakage.	Wait till the end of test.
Pneum test over	The test for air leakage is finished.	None
Measurement over	START is pressed during measurement.	None
Reset failed	The NIBP module fails to be reset.	None
OUTPUTTING...	Data are being output.	None
CONNECTING...	The monitor is connecting to the PC software.	None
OUTPUT SUCCESS!	Data output is finished.	None
Standing by failed	The monitor does not meet the conditions for entering the standby state.	None

Appendix D Symbols and Abbreviations

D.1 Symbols

A	ampere
Ah	ampere hour
bpm	beats per minute
℃	centigrade
cm	centimeter
dB	decibel
℉	fahrenheit
g	gram
hr	hour
Hz	hertz
inch	inch
k	kilo
kg	kilogram
kPa	kilopascal
l	litre
lb	pound
m	meter
mg	milligrams
min	minute
ml	milliliter
mm	millimeters
mmHg	millimeters of mercury
ms	millisecond
mV	millivolt
mW	milliwatt
nm	nanometer

s	second
V	volt
VA	volt ampere
Ω	ohm
µA	microampere
µm	micron
µV	microvolt
W	watt

-	minus
%	percent
/	per; divide; or
-	to
^	power
+	plus
=	equal to
<	less than
>	greater than
≤	less than or equal to
≥	greater than or equal to
±	plus or minus
×	multiply
©	copyright

D.2 Abbreviations

AAMI	Association for Advancement of Medical Instrumentation
AC	alternating current
ADT	adult
ANSI	American National Standard Institue
AUX	Auxiliary output
BTPS	Body temperature and pressure, Saturated
CH	channel
CISPR	International Special Commmittee on Radio Interferennce
CMS	central monitoring system
cmos	Complementary Metal Oxide Semiconductor
CPU	central processing unit
DC	direct current
D, DIA	diastolic
EEC	European Economic Community
EMC	electromagnetic compatibility
err	error
fpga	Field Programmable Gate Array
Hb-CO	Carbonmono-xide hemoglobin
HT	height
IEC	International Electrotechnical Commission
ISO	International organization for standardization
LED	light emitting diode
Loop	loop read-write test fail
M, MEAN	mean pressure
MDD	Medical Device Directive
MetHb	methemoglobin
Mii	initialize MII registers fail

MRI	magnetic resonance imaging
N/A	not applied
NIBP	noninvasive blood pressure
oxyCRG	Oxygen Cardio-respirogram
P	power
PD	photodetector
PLETH	plethysmogram
PR	pulse rate
RAM	random access memory
Reg	test NE2000 registers fail
ROM	read-only memory
SpO_2	arterial oxygen saturation from pulse oximetry
S, SYS	systolic pressure
T	tempertature of channel 1
TD	temperature difference
TEMP	temperature
VGA	Video Graphice Array